October | November 2010
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FoodSafety magazine

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Food Safety Legislation: Where Are We?

Controlling *Listeria* in RTE Meat and Poultry

Is Your Calibration Program Effective?

Insider: Solutions in Rapid Microbiology

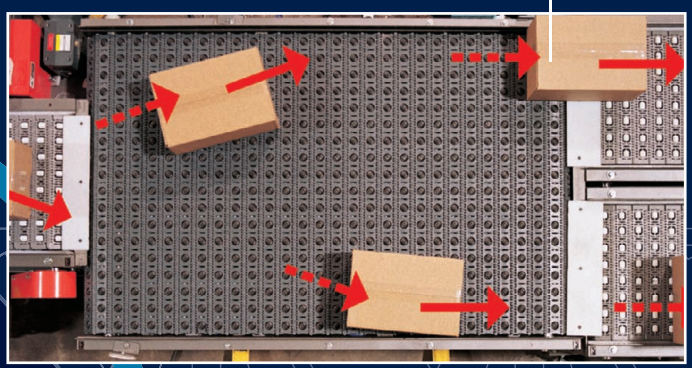
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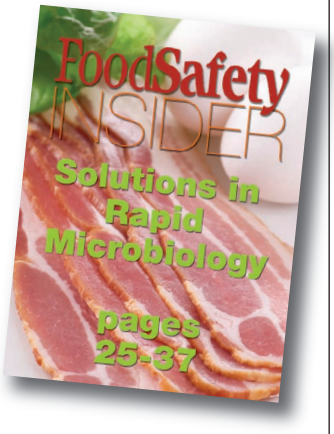


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FROM THE EDITOR

Fall is the time of year that brings many things to mind: leaves changing color (a big deal here in New England!), cooling weather, a spate of holidays and, of course, elections and politics. Ignoring for a moment the midterm elections (if you can), one Washington D.C.-related item we should *not* ignore is the future of food safety legislation.



It is disappointing to note that the United States Senate has decided *not* to take up the Food and Drug Administration (FDA)'s Food Safety Modernization Act before the midterm elections, according to a recent news release from the Food Marketing Institute.

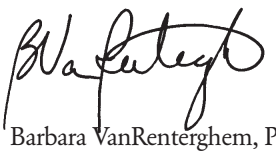
I don't think there's any disagreement among those in the food industry (or even among consumers, for that matter) that bi-partisan food safety legislation should have already been passed in Congress. Given the plethora of product recalls that blanket the news far too often, it is certainly time for this country to focus on balanced solutions that will both prevent food safety problems at the source *and* protect our global food supply in the future.

While there are arguments for industry to police itself (and by and large, the food industry has done a good job), we only need to look at the financial, housing and energy industries to know that *some* regulation is, in fact, *good* regulation. Providing the FDA with the necessary resources and authority to enforce the current regulations would be a step in the right direction. But just what potential food safety legislation may look like is still unknown.

Our cover story this issue both asks and attempts to answer this question in terms of the effects of the pending food safety legislation on product traceability. Drawing from her experience in food microbiology and at the Institute of Food Technologists, Jennifer McEntire, Ph.D. analyzes the issues presently confronting the industry, the current food regulations and where we stand today. She also offers some clarification of the pending bills and what their enactment would mean to the industry, identifying the challenges still ahead and offering her suggestions as to where we should go next. Her dissection of these issues is very timely, in light of the political changes that appear to be on the horizon.

No matter what your political bias, I think there is one thing we can all agree on: food safety is the ultimate goal. We may differ in our opinions as to how we get there, but working in the same *forward* direction seems like a good place to start.

Best Regards,



Barbara VanRenterghem, Ph.D.
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Pan-American Nutrition Award 2010

The Pan-American Nutrition Award 2010 recognizes the best research papers of the year in the fields of human nutrition and food science and technology. Awarded only bi-annually, the awards are granted to both established professionals and young scientists in the four zones served by Grupo Bimbo: the United States of America, Mexico, Central America and South America.

Each zone will have two winners: professional and young scientist.

- Young scientist: Must have concluded a Master's Degree, maximum 2 years before publication date of the invitation for award and must actively participate in important scientific and or tech research projects; must have at least one publication in a peer-reviewed journal. Prize $2,000.00/zone.
- Professional: Must have carried out unique, valuable research projects alone or as part of a team, with at least five peer-reviewed publications in the last 3 years and have supervised postgraduates; must have taught and participated in activities promoting science. Prize $5,000.00/zone.

Award submissions should be registered at premiopanamericano.grupobimbo.com. The deadline to submit papers is October 15, 2010. Contestants may submit multiple applications. An independent Scientific Jury from each geographical zone, composed of renowned researchers and experts in human nutrition, food science and technology, will rate the submitted projects based on the evaluation criteria. The projects with the highest ratings will win the awards.

NEWS FLASH:
Highlights of the FSM eDigest

Articles in our September eDigest (available at the eDigest archives at **www.foodsafetymagazine.com/exclusives.asp** focused on the issues of recall preparedness and traceability programs, topics that go hand in hand for processors who wish to be on top of protecting their brands.

Coming up in our October eDigest will be an article on *Anticipating Changes in Food Packaging* by Richard Fama, a member of the food liability practice group at law firm Cozen O'Connor. Changes in food packaging technology will be discussed.

PortaFab Modular Building Systems Achieves ISO 9001:2008 Certification

Portafab Modular Building Systems was assessed by NSF-ISR, Ltd. earlier this year and found to be in conformance with ISO 9001:2008 standards. The company manufactures environmentally friendly modular construction products and provides technical support to architects, contractors and developers in the construction industry.

Organized into integrated systems that streamline the construction process and provide nearly unlimited flexibility, PortaFab's modular components are used extensively in the construction of inplant offices, modular cleanrooms, dry rooms, wall partitions, demising walls and pre-assembled buildings.

Significant growth in supplying high-tech manufacturing industries and the increasing application of Portafab's modular systems in creating cleanroom and environmentally controlled areas served as a catalyst for achieving ISO 9001:2008 certification.

Recent Articles Available Online at
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Water quality is of critical importance for food and beverage manufacturers. Read *Food and Beverage Manufacturers Tap into Industrial Water Treatment Solutions to Help Meet Sustainability Goals* by Ed Orvidas from Culligan International to learn more about food plant water-saving strategies.

A case study of mustard maker G.S. Dunn *(Case Study: G.S. Dunn Quality Control Facility in Hamilton, Ontario)* shares tips for saving energy and improving quality assurance by employing LED high bay fixtures by Dialight.

Seeing product go to waste means a loss of profit, which can impact the bottom line. Read the article by United Air Specialists on *Smart Dust Collection: Reducing Ingredient Shrinkage*, which profiles how Allied Blending & Ingredients successfully reduced product waste, while keeping the facility dust-free and reducing dust collection system maintenance costs.

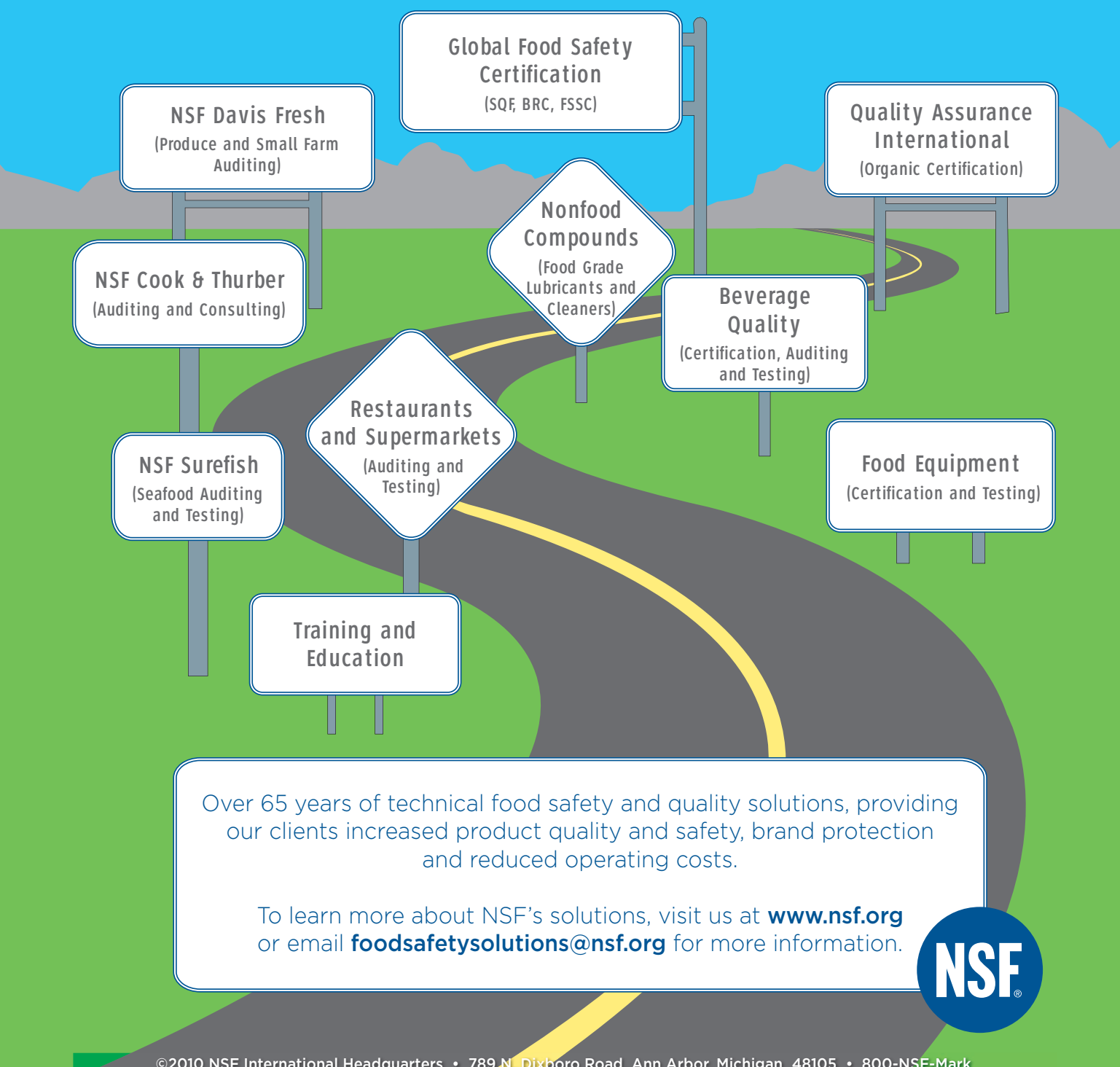
AIV Forms Strategic Alliance with Crozier-Dodson Food Safety Consulting

AIV Microbiology & Food Safety Consultants, LLC, a provider of food safety management and technical solutions to food industry and government customers worldwide, has announced a strategic alliance with Crozier-Dodson Food Safety Consulting, LLC (CDFSC) to provide specialized food safety and microbiology training to global food industry clients.

Under the agreement, CDFSC will develop a menu of new and innovative food safety and microbiology short courses and workshops to support all aspects of AIV's consultancy services. Beth Ann Crozier-Dodson, Ph.D., president of CDFSC has extensive experience as an independent consultant, teaching microbiology and food safety workshops throughout the world. Her expertise also includes work as the assistant director of the Kansas State University International Food Microbiology Rapid and Automated Methods Workshop for 16 years, which was founded by Dr. Daniel Y. C. Fung.

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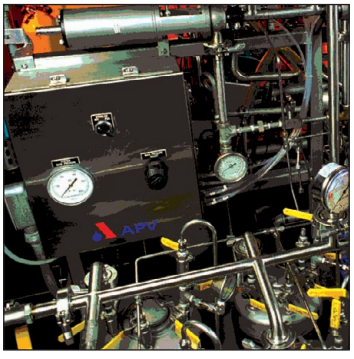
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By Richard F. Stier

Building an Effective Calibration Program

Calibration: *The comparison of a measurement instrument or system of unverified accuracy to a measurement instrument or system of known accuracy to detect any variation from the required performance specification.*

–American Society for Quality



It is absolutely essential that calibration be an integral part of a food or ingredient processor's quality and safety program. Almost all regulations and management standards that address food quality and safety include language that stresses the importance of calibration. The low-acid canned food regulations found in the U.S. Code of Federal Regulations 21 CFR Part 113 reference the need for calibration:

"Each thermometer should have a tag, seal or other means of identity that includes the date on which it was last tested for accuracy."

As does the Hazard Analysis and Critical Control Points (HACCP) regulations that are mandated for meat and poultry, seafood and juice:

"Records that document the calibration of process monitoring instruments."

And, finally, ISO 22000, the food safety management system's requirements for any organization in the food chain, states in Section 8.3:

"The organization shall provide evidence that the specified monitoring and measuring methods and equipment are adequate to ensure the performance of the monitoring and measuring procedures."

The bottom line is that all instruments used for ensuring quality, safety, sanitation and legal compliance must be calibrated. In addition, if there are monitoring devices that are necessary to ensure worker safety and/or safe operation of equipment, they must be included in the calibration program. An example of such a device would be a pop-off valve on a pressure vessel.

To achieve this goal, processors need to perform the following:

- Develop effective procedures for calibration;
- Document those procedures;
- Maintain records of calibration activities, including corrective actions;
- Review records to ensure that procedures are being followed;
- Observe the employees doing the calibration procedure to ensure they are following the procedures; or, audit third parties contracted to do similar work.

It is also important to assign someone to manage the calibration program to ensure that it is properly designed, implemented and maintained.

Who Manages the Program?

So, who should manage the calibration program? This depends on each and every company. What happens frequently is that processors do not assign an individual to manage the calibration program, but allow it to be done by different operating groups. The production people might be responsible for unit operations such as metal detectors or magnets, whereas engineering takes responsibility for temperature-indicating devices (TIDs) and pressure gages. The quality manager or laboratory supervisor will ensure that the instruments in the laboratory are properly calibrated. There may be other groups that get involved. For example, the warehouse people might be responsible for looking after refrigerators, freezers and relative humidity controls.

What can happen in a situation like this is that there are many different calibration programs that use different forms and procedures. In addition, there may be critical instruments that "fall through the cracks" and are either not being calibrated or not being calibrated frequently enough to adequately ensure safety or quality. It is okay to have different persons responsible for their areas, but one person needs to manage the entire program. His or her role is to ensure that there is a consistent program that addresses all calibration activities that need to be done to ensure product quality and safety. The calibration manager needs to work with his group to establish a standard format for procedures. The manager must also evaluate all monitoring instruments in the plant and determine not only whether calibration is necessary, but how often this should

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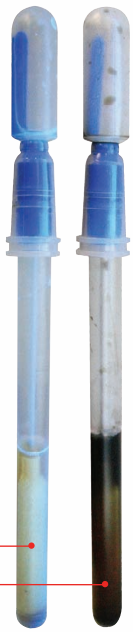
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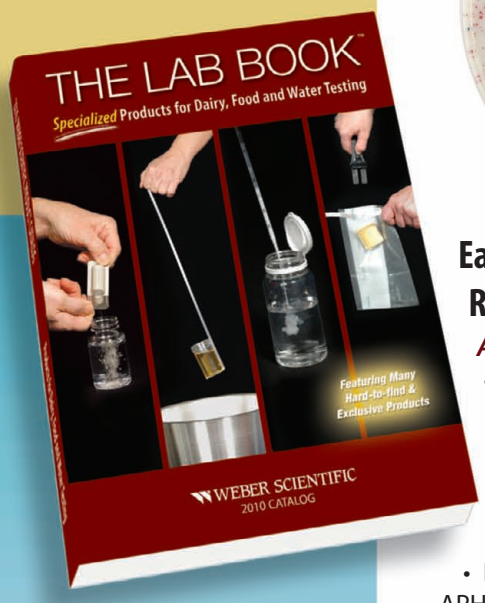
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be done. By conducting a risk assessment, they can determine not only which devices are essential for the production of safe, wholesome and high-quality products, but also whether the procedures are being employed properly.

The job description of the manager responsible for calibration should clearly state that this individual is responsible for managing the program. He or she must accept their job description, acknowledging responsibility. Among their duties will be to ensure that the program remains on schedule, that it is audited per established schedules and that calibration records are being reviewed per established schedules. In addition, the calibration manager must ensure that all persons responsible for calibrating instruments or ensuring that they are calibrated have been trained on the procedures and/or work instructions required to do the work and that records of these sessions are maintained.

Developing and Documenting Procedures

It is absolutely imperative that all procedures involved in the calibration program be documented. There should be a general protocol that describes how the calibration program will be developed and implemented, plus work instructions that describe how each instrument or class of instruments should be calibrated.

The general protocol should include the following elements:

- Objective of the program
- Responsibility
- Calibration procedures
- Documentation responsibilities
- Corrective actions

Each work instruction should include step-by-step procedures on how the calibration should be done, the standards that will be employed, the tolerances and how the results shall be reported. If the instrument is out of calibration, the procedures must not only describe what will be done with the instrument, but more importantly, it must address what to do with any product that might be affected. Most operations "tag" their instruments after calibration. The calibration tag may include who did the work, the date the work was done and the date of the next scheduled calibration. These tags should be made of materials that are water- and oil-resistant so they will survive the rigors of production, including cleaning. Additionally, if tagging is part of the program, removal of outdated tags and replacement with new ones should be included in the procedures.

"It is absolutely **essential** *that calibration be an integral part of a food or* **ingredient** *processor's quality and safety* **program."**

With instruments such as pressure gages or TIDs, it is best to calibrate the unit at three points that bracket the normal operating parameters. The risk assessment exercise should be used to help establish how to calibrate the instrument.

There is a difference between calibration and verification. Perhaps the best example to use when differentiating the two is a scale. Scales are usually calibrated one or two times per year by a regulatory agency or a licensed calibration organization. These groups test the units against known standards and adjust them as needed. Many operations routinely verify their scales. To do this, they routinely check performance using standard weights.

Calibration procedures must address instruments used for monitoring process operations and performing quality tests, and any standards used in-house. Processors must send standard thermometers (National Institute of Standards and Technology or American Society for Testing and Materials), weights and other devices to an outside agency for calibration at regular intervals.

Procedures for sending instruments out must also be documented. If a state agency comes into your facility once a year to calibrate scales, load cells and other devices, procedures describing how this is done, who is responsible and what needs to be done if the instrument is found to be out-of-calibration are necessary

One of the most valuable tools for documenting and organizing a calibration program is a master calibration schedule (Table 1). Rolling all instruments that require calibration into this master list allows a processor to easily monitor the program and makes life much easier for auditors. The whole program is summarized in one document. Of course, hard copy records of calibration records must be available for review and to verify that the work was not only done, but done properly.

Records and Corrective Actions

Records of all calibration activities must be maintained either as hard copies or electronically. Many processors roll their process instrument calibration into a maintenance management software program. These systems are available commercially or can be developed internally using programs such as Excel™ or Access™. If your company decides to purchase or build an electronic system to maintain and monitor a calibration program, consider incorporating the following features:

- Maintenance scheduling
- Flags when items are due
- Flags for past-due items
- Procedures for doing work
- Automatic entry by workers
- Ability to have records scanned and accessed by the system

Instrument	Serial #	Location	Frequency of calibration	Test method	Standards/ tolerances	Person responsible	Date last calibration	Date next calibration	Comments

Table 1: Master Calibration Schedule

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- Ability to verify that work has been done
- Print capability: summaries, schedules
- Ability to "talk" to other systems

Be forewarned, however, electronic maintenance management systems take a great deal of time and effort to get up and running. There is a huge amount of information to input into the system. In addition, it is absolutely imperative that several persons be trained to manage and use the system. This is one situation where "putting all your eggs in one basket" can be huge mistake. I have seen such systems abandoned when the only trained person leaves the company.

As noted above, calibration records are mandatory for all instruments used to monitor Critical Control Points (CCPs) in a HACCP program. In addition, the importance of developing documented calibration procedures that include corrective actions cannot be overemphasized. One of the gaps observed in many calibration programs is that the corrective actions do not include what to do with product that may be affected. The protocol may contain statements like the following:

"If the instrument is not in calibration, make the necessary adjustments to bring it back into calibration and retest," or

"If the instrument is out-of-calibration, take it out of service and send it to the vendor for repairs. If it cannot be repaired, replace it immediately."

It is imperative that the procedures address any product that might be affected. Here is an example: many years ago, a processor of acidified peppers, a seasonal item, received a visit from the U.S. Food and Drug Administration (FDA) at the end of the season. The company's records indicated that all of the products packed throughout the season had a pH of 4.6 or below. When the FDA began checking the pH values of products, they found pH values of 4.8 and above. These findings indicated that the product was potentially unsafe as it could support the growth of *Clostridium botulinum*. Unfortunately, the company had no records documenting that their pH meters had been calibrated. The company said that they did it each and every day, but they had failed to document that the work had been done. The FDA told them to embargo the entire season's pack and develop a sampling plan to show compliance. The company elected to destroy the entire season's pack, estimating that the testing would cost too much. So in this case, a failure to maintain proper calibration records cost a company a full season's pack.

There are many instruments or pieces of equipment that processors look to outside agencies to calibrate, which may include scales, load cells, TIDs and others. If an outside agency does the work, make sure that their reports include the method used for calibration, tolerances, any adjustments or actions and results. Simply sending a report that the instrument is satisfactory is unacceptable.

Record/Review Verification of the Program

The pepper packer scenario discussed above is an excellent example of the im-

(continued on page 57)

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By Robert W. Powitz, Ph.D., MPH

Lessons Learned and a Bit of History



I just celebrated my third anniversary as a Medicare cardholder. The time has finally come to sit back and relax a bit and let a younger, more energetic and better-trained generation launch us into the next era of food safety. I've earned the right to make those difficult choices about whether to meet publication deadlines or go fishing. So now is a good time to cut bait and forget the flashing icon on my computer screen. No, I'm not putting away my thermocouple thermometer or holstering my brand new LED flashlight just yet. I still enjoy being a sanitarian too much to leave this exciting profession entirely; as the playwright Noel Coward once said, "Work is more fun than fun," and I fully intend to keep the fun going until I can't anymore. But just before the fat lady sings, I would like to present a little bit of local regulatory history of the food safety movement as I lived it, and perhaps give a little insight into the future.

Views from the Past

Forty-five years ago I started working as a district sanitarian for the New Jersey State Department of Health. There were eight of us who covered the state in four health districts. Our job was to inspect all state-licensed food establishments and to serve as a resource (most often playing the role of "Bad Cop") for the local sanitary inspector who, for whatever reason, was faced with a recalcitrant retail food proprietor. Occasionally, we were the 'epidemiologists du jour' charged with chasing after foodborne misadventures. Our entire approach to food safety was quite different than it is today. Our main focus was on food adulteration, rather than contamination, and we were very much into the "walls, floor and ceiling" mentality with regard to sanitation. I came into the profession at the tail end of *The Jungle* (Upton Sinclair's 1906 novel) era.

The references we had reflected the food protection philosophy at the time. I recall using the 1962 Public Health Service (PHS) *Foodservice Sanitation Manual* as my basic marching orders, a briefcase full of NSF standards as enforcement adjuncts and a copy of Ehlers & Steel's *Municipal and Rural Sanitation* as a text reference. As state sanitarians, we were lucky to have copies of the National Association of Sanitarians' *The Sanitarian's Desk Reference* and Dr. Ben Freedman's *Sanitarian's Handbook* in our office. These were invaluable references when everything else failed.

Our food safety field instrumentation consisted of a bimetal thermometer and a maximum-registering, mercury-filled thermometer in an armored case. That was it. The rest of our gear included a Hobart fat tester, hydrometer, brix and salinity refractometers; a dropper bottle filled with a Malachite Green solution to detect sulfite adulteration in meats; a phosphatase milk testing kit, Mason jars and sealing wax for taking food samples; and a WWII Army surplus metal oil can that was filled with the foulest smelling kerosene to ensure that condemned foods stayed condemned. All this was hauled around in a '55 Dodge. The tools provided intrigue when I found violations and the Dodge provided the comic relief. Damn, I loved that job.

Forward Ho!

In 1976, the second iteration of the PHS *Foodservice Sanitation Manual* was issued. It did several important things for those of us in local enforcement, particularly in the way our profession started looking at the retail food industry. Yes, it still emphasized the good ol' walls, floor and ceiling sanitation paradigm, but it also introduced, albeit sub-

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tly, cross-contamination protection and an emphasis on the control of potentially hazardous foods. It was then that I became fascinated with the concept of using both time and temperature as a means of preventing foodborne illnesses in the retail trade. Unfortunately, the '76 code did not include Hazard Analysis and Critical Control Points (although it certainly was around at that time) or specifics on contamination control. For these, we had to wait until the 1995 Food Code was issued. As a result, much of our enforcement activities were based on what the legal profession cobbled together in the form of case law and lawsuits filed in response to a spate of foodborne illness outbreaks. Seeking redress through the courts was far more expeditious than going through regular governmental channels when it came down to actual food safety.

In about 1980 when I was fairly fresh out of graduate school, I had my first experience as plaintiff's expert witness in a case involving foodborne intoxication. The defendant's counsel was a seasoned criminal trial lawyer, and I learned, perhaps the hard way, the importance of knowing the art and science of my profession and using my knowledge, skills and attributes to the best of my ability. I can distinctly remember being asked by the opposing counsel whether I had written anything for which I professed expertise. At the time I hadn't, and the rest of that session was a battle of wits between attorneys as to whether or not I was qualified to render the opinions I had put in my report regarding my findings in the case. Although our side prevailed, it was about as uncomfortable as sitting on a fire ant hill. This scenario was not so much about my credentials, but rather it had more to do with the lack of information available to both the retail food industry and legal community when dealing with the aftermath of an unintentional incident as well as developing a prevention model so that it would not happen again. However adverse this situation was, it served as a wakeup call. So, for the past three decades, I have doggedly written about environmental health and safety issues and conditions in institutions and retail food establishments that are not found in text books, journals or in the popular press. I've always made it a point to address something that I had recently encountered in plying my profession, or what I saw as the next new idea in controlling risk. Needless to say, it's been quite rewarding.

A Fond Farewell

So, I gently bow out of another era, one in which we've witnessed significant changes in attitudes, policies and practices. We've seen significant initiatives in consumer protection, and we have begun to question the whole issue of "farm to fork" and sustainability. This will be our future. In thinking ahead, I realize that our science has barely scratched the surface in working with food safety, including embracing the Green movement. There is so much left to do, so many things to find out about food safety strategies and so many ways to discover how to control risks in new cost-effective and cost-efficient ways. Hopefully, we will all seize the opportunities in this field and run with them. We're bound only by the limits of our imaginations.

Finally, I want to thank all my readers for their support and particularly those who provided feedback…good, bad and indifferent…about my work. I sincerely appreciated every comment, recommendation and suggestion. I've enjoyed exchanging ideas, and most importantly, I've learned so very much from all of you. I would like to think that we've all made a difference for the better.

With warmest regards,
Bob Powitz, Sanitarian ■

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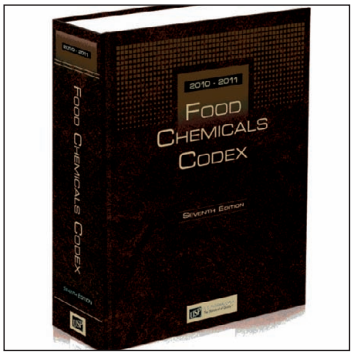
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By James C. Griffiths, Ph.D. and Markus Lipp, Ph.D.

Meeting Consumer Demands while Maintaining a Safe Food Supply

The food business is one of the most exciting industries to be a part of today. To address consumer preferences and needs, the food industry needs to continuously develop new products, new processes and new supply chains at a rapid pace. New advances that broaden consumer access to an array of foods seem to come to fruition continuously—from novel sweeteners and salt substitutes to international flavors to the ever-growing category of functional foods and beverages.



Consumers are increasingly demanding–they want tasty food that supports good health, they want seasonal food year-round, they want food incorporating the flavors of the day (yesterday's pomegranate is today's açaí), they want food in convenient portions and packaging that suits their busy lifestyles and they want food at low prices, particularly given today's economic realities. Manufacturers must work hard through innovations, improved processes, business functions and new supply chains to meet these expectations–many of which the manufacturers set themselves through the marketing of their products. Of course, underneath it all, there is the ultimate consumer expectation that goes without saying: that the food available for purchase is safe. However, this may very well be the toughest challenge of all to meet, given the complexities of modern food production, ingredient sourcing and product distribution through long and complex supply chains.

A safe food supply requires several different elements, which have been highlighted quite comprehensively in previous articles. These include regulatory bodies equipped with appropriate resources, ethical manufacturers and suppliers, tightly managed supply chains and the existence of and adherence to independent standards of quality. When we speak of foods, we speak not only of finished food products but also of the various ingredients that comprise these foods–which, of course, can impact overall product safety and quality. As is common wisdom for food producers, it is much easier to control the end-product by ensuring safe ingredients and processes than by testing the end-products for safety.

Focus on Food Ingredients

The U.S. Pharmacopeial Convention (USP), as an independent, standards-setting body, promotes public health by publishing standards for the identity, quality, purity and consistency of food ingredients via the *Food Chemicals Codex* (*FCC*) compendium. With these ingredients–such as colorings, flavorings, nutrients, preservatives, processing aids and sweeteners–continuing to play an increasing role in the modern consumer's diet, ensuring their quality is essential as the industry seeks to assure safety to consumers.

Because we hear far less about food ingredient quality and safety than, say, microbial contamination of fruits, vegetables and meats, the question becomes whether there is actually a need to focus time, energy, expertise and resources to this area. The answer is yes. This has been proven through the problems that have received widespread media coverage over the past few years, such as infant formula and pet food adulterated with melamine–incidents that harmed consumers and pets–caused by the undetected hazard that was intentionally introduced into the food supply chain as an adulterant to a bona fide food ingredient for pure economic gain. This example not only demonstrates clearly the hazard of an unsafe food ingredient, but also the wide segments of consumers and industry that are detrimentally exposed and harmed from such action. Long supply chains contribute further to these crises by making it difficult to directly pinpoint and isolate the source of the problem. The outcome was tragic for the affected consumers and devastating for the industries im-

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pacted by it. Therefore, preventing such incidents is a priority not only to safeguard consumers against grievous harm, but also to protect brands and brand names for the industry. Exactly at this junction, where quality defects impact the safety of food ingredients, the quality standards of the *FCC* are a critical aid to the industry and ultimately to the consumer to ensure the appropriate quality of food ingredients and to maintain trust that our food supply is safe.

Beyond these types of incidents, there are other quality issues, which may not garner such extensive attention, but that nevertheless can still be serious. "Quality" takes into account a host of factors: that the ingredient is what it claims to be (identity); that it is not a contaminated, adulterated, diluted or otherwise inferior product; and that it is consistent from batch to batch. These may affect the safety of a product–or may influence the taste or texture of a product or other factors that may not harm a consumer but may result in their rejecting a product or brand. That is something no manufacturer wants.

Focus on Standards—Finding Common Ground

Ingredients are produced around the world, and manufacturers source their ingredients from a host of countries. Global sourcing is a strategy that most manufacturers pursue to minimize costs and to secure a single (or more) source for their global needs. This further ensures that the manufacturer benefits from the economy of size to answer to consumer interest in ever-lower prices. As a consequence, one product could contain ingredients produced in 10 or more countries. This poses a formidable challenge to food manufacturers. What sort of assurance does a manufacturer have that an ingredient is what it claims to be? How does a manufacturer know it is getting what it paid for? Economics are key factors in the food business, but do we need to ask if there is a reason why one source of an ingredient is less expensive than another?

Take extra virgin olive oil. Some estimates conclude that there are not enough olive trees in the world to account for all the purported extra virgin olive oil being sold today. (To improve the situation regarding adulterated extra virgin olive oil in the United States, the U.S. Department of Agriculture recently issued new standards tightening the requirements for the product.) The same goes for pomegranate juice. What this means is that finished product manufacturers–and consumers–may not be getting what they paid for. Some seem to be getting a low-quality product, and the consequences can range from safety concerns to taste, texture or other implications. As we've discussed in a previous column,[1] a major incident could result in a recall, and even a comparatively minor episode (e.g., one that impacts taste but not safety) could result in a consumer switching brands or rejecting a product. With fierce competition in the food market, it will be very challenging to bring back those consumers once they have switched brands.

"To address consumer **preferences** *and needs, the food* **industry** *needs to continuously develop new products, new* **processes** *and new supply* **chains** *at a rapid pace."*

One can also look at the flip side of this scenario. How does an ethical ingredient supplier differentiate itself from other suppliers who may be pushing less-expensive versions of the "same" ingredient that may be of questionable quality? How does an ethical supplier protect itself, its products and the buyers of its products?

This is where independent standards, such as those provided by the *FCC*, come into play. With the availability of an independent standard to define and assess the authenticity and quality of a food ingredient, suppliers and manufacturers can more easily meet each other's expectations with regard to critical quality attributes. Manufacturers can demand that their products adhere to an *FCC* standard, and suppliers can use their adherence to these standards as a means of differentiation. As new ingredients emerge, as pressures to keep food prices low continue and as the globalization of the industry persists, ensuring quality can become very difficult. Independent quality standards can be a key part of supply chain management. Observance of these standards may be used in conducting day-to-day business transactions as part of contracts, for instance. They also may be used for maintaining regulatory compliance in all of those countries that recognize the *FCC* in law.

Focus on Infant Formula

Infant formula offers an ideal case study on the importance of ensuring quality, for many reasons. First, the margin of error here is very slim given the end consumer is part of a highly vulnerable population. Second, formula is designed to be the only source of nutrition for infants, making it critical that they are receiving all the ingredients and benefits of the product necessary to sustain good health and development. Typically, the infant's diet is not supplemented elsewhere during this pivotal period. Furthermore, the ratio of food to body weight in infants is significantly higher than in adults. Their undeveloped organs do not possess all the metabolic clearing pathways of an adult, making them much more susceptible to potential health risks. Third, infant formula is an area where consumer trust is absolutely critical; no parent wants to compromise the safety of their children. If a product were to be subject to a recall or any public questioning regarding its quality or even safety, it would be very difficult for a manufacturer to earn back that trust. Fourth, infant formula has undergone various innovations and major improvements over the years, including enhancing the product with specific ingredients such as nucleotides (which are present in higher doses in human milk than in cow-based infant formulas–and are thus routinely added to infant for-

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mulas today) and docosahexanoic acid (DHA) and arachidonic acid (ARA) oils. DHA and ARA oils contain essential omega-3 fatty acids present in fish and are frequently added to both infant formula and a host of functional foods for their claimed benefits in maintaining good health and development. As new information has emerged over the years regarding the benefits of these ingredients, parents often consciously select infant formula products that contain these ingredients. Furthermore, supplementing infant formulas with DHA and ARA is supported by the World Health Organization at levels of 0.35% and 0.7%, respectively. U.S. infant formula manufacturers began to offer formulas containing DHA and ARA in 2002.

Quality standards serve an important function here. Consumers deserve to know the product they are feeding their infants contains ingredients that are pure and of high quality–as do manufacturers who seek to provide the best possible product to their customers. In January 2010, USP announced it was proposing new standards for three nucleotides and two DHA oils. The three new nucleotide standards were for disodium 5'-uridylate, 5'-adenylic acid and 5'-cytidylic acid. The new standards for DHA oils were for DHA algal oil, *Crypthecodinium* type and DHA algal oil, *Schizochytrium* type. The distinction between the two DHA algal oils is essential as the first can be used in infant formulas as well as for a wide variety of other products considered functional foods; the second is used for functional foods but cannot be added to infant formula. Following a period of public comment in which manufacturers and others were invited to review these draft standards and provide input (as per the public process through which all *FCC* standards are proposed and reviewed), these standards were subsequently published this past August in a supplement to the *FCC*, and will become effective November 30, 2010. USP's monographs also contain all analytical methods necessary and suitable to verify compliance with the monograph's quality specifications. Additionally, USP offers reference standards (authenticated chemical specimens) for the nucleotides, thus enabling any test laboratory to confirm the correct execution of laboratory procedures used for the verification of the quality specifications. USP thus does not just set quality standards, but also offers all the necessary tools to verify both compliance with such standards and the correct execution of such procedures as demanded in quality systems for test laboratories, such as those required under ISO 17025.

Focus on "The Big Picture"

With infant formula, as with all ingredients, the case for quality standards is compelling. Quality standards serve a unique function. Those provided by the *FCC* are independent, scientifically developed, public standards, often with associated reference standards. Food manufacturing is global, providing opportunities for good (e.g., expanding consumer access to foods and promoting new nutritional enhancements), but also introducing complexities that can have negative and sometimes catastrophic effects. Consumers can and should expect new innovations, but above all, they expect food to be safe and require food products they can trust. Manufacturers also need assurance that they can trust the ingredients they source (and their suppliers). Additionally, ethical suppliers may require a means to prove their ingredients' quality. Standards can play a significant role for all these parties, contributing to a better–and safer–food supply. ■

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By Aqualia L. Nelson, MS, REHS/RS, Aiko Allen, MS, Suzanne R. Hawley, Ph.D., MPH, Theresa St. Romain, MA and Shirley A. Orr, MHS, ARNP, NEA-BC

Creating a Positive Partnership Between Foodservice Establishments and Inspectors

The restaurant industry has a significant impact on environmental health, and the magnitude of that impact has been increasing in recent years. Americans' dependence on restaurants is noteworthy; on average, 48% of money spent by Americans on food goes toward restaurant meals.[1] As a result, in 2009, projected restaurant food sales grossed $565.9 billion, and 9% of the national workforce was employed at approximately 945,000 restaurant locations across the United States.[1]



The combination of these factors has led to a greater potential for foodborne illness (FBI) due to improper food handling; that is, contamination by other foods or by food handlers themselves.[2] With this heightened risk comes the need for increased food safety sanitation efforts. In recent years, the Centers for Disease Control and Prevention has formed numerous national-level partnerships between key restaurant industry stakeholders.[3] However, much of the responsibility for ensuring the safety of restaurant food still rests on the shoulders of one party: the local-level environmental health specialist (EHS), commonly known as a food inspector.

EHS are responsible for local inspection-related activities to promote safety and prevent outbreaks. They generally employ a combination of educational and enforcement techniques, as well as legislative and regulatory approaches, to correct violations. Previous research has shown that the education of food workers is far more effective in promoting safe behavior–including proper food preparation–than is enforcement.[4] However, education alone does not guarantee that food workers will employ safe food-handling practices.[5,6] Studies have indicated that additional local interventions, such as increased inspection frequency and food safety certifications, are necessary to improve sanitation in restaurants.[6-8]

Traditionally, the relationship between EHS and restaurateurs has been adversarial, often due to assumed differences between the two groups. Foodservice workers frequently fear the inspection process, believing that the mission of EHS is to find violations and reprimand, rather than to work collaboratively toward a common goal of food safety. As a result of this sometimes tense relationship between EHS and foodservice employees, traditional regulatory approaches do not necessarily ensure the adoption of desired food safety behaviors.[9] Non-traditional approaches, such as announced inspections, emphasize the importance of food safety, rather than focusing on compliance with regulations, and have proven to be more successful than traditional approaches to restaurant regulation.[10]

To date, an understudied area remains the knowledge, attitudes and intentions of EHS and restaurateurs that may influence their willingness to collaborate on food safety at the local level. This study, conducted in Johnson County, KS, utilized a survey and focus groups to assess the attitudes of EHS and restaurateurs toward one another, and examined barriers to and methods for creating partnerships between the two groups.

Methods

Study Setting

Johnson County is an urban county in northeast Kansas that includes several suburbs of the Kansas City metro area. Johnson County contains 1,467 foodservice establishments: restaurants, schools, mobile units and 231 retail foodservice establishments, which include grocery and convenience stores.

Survey Participants and Instrument

Seven EHS, under the auspices of the Johnson County Environmental Department (JCED), are responsible for

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conducting inspections at foodservice establishments in Johnson County. These EHS conduct a variety of inspection activities that include routine, follow-up, complaint, courtesy, disaster, Hazard Analysis and Critical Control Points (HACCP), modified complaints, plan review and FBI investigations.

A Johnson County EHS developed a survey with the input of a biostatistician, public health consultant and a food inspector with 25 years of experience, and administered the survey to the other six EHS. The 32 survey items assessed current workload, the inspection process, communication efforts, training, compliance/enforcement actions and relationship between EHS and dining establishments. Answers were reported on a five-point Likert scale ranging from "Strongly Disagree" to "Strongly Agree," or from "Very Dissatisfied" to "Very Satisfied," depending on the item.

Focus Group Participants and Instrument

Foodservice employees were recruited randomly for focus groups from among the pool of restaurant employees in Johnson County. Recruitment occurred through letters, emails, telephone calls and onsite requests. Restaurateurs were asked to participate voluntarily and were informed that the purpose of the focus groups was to obtain their opinions and suggestions on services, barriers and ways of creating partnerships. The final pool of 21 focus group participants included three kitchen managers, one chef, two lead preparation workers, nine general managers, two district managers, two establishment owners, one Director of Operations and one whose position was not reported.

A list of discussion topics was developed by the researchers and was partially influenced by responses from the above-mentioned EHS surveys to ensure that potential areas of convergent or divergent opinions were addressed (Table 1). Common issues such as services provided, educational material, enforcement actions and barriers faced were placed on both the survey and focus group questionnaire.

Procedures

The survey was administered to six Johnson County EHS. Respondents were given a copy of the survey, then asked to complete it in a private room and place it in an unmarked collection envelope for the research team. After all six respondents completed the survey, responses were collected and descriptive statistics analyzed.

Three focus group meetings with 21 participants were conducted at the JCED in Olathe, KS. Each focus group lasted approximately 1.5 hours. Participants engaged in an open discussion of questions posed by a group moderator. Topics discussed by participants included: 1) services provided by Johnson County EHS/food inspectors; 2) materials, training and educational tools provided by EHS; 3) enforcement and compliance actions taken when food code violations exist; 4) barriers to food safety within the industry; and 5) ways to create positive partnerships with EHS. Items for discussion were chosen based upon their direct influence on the rap-

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port established between EHS and restaurateurs.

Focus group discussions were recorded on audiotape and then transcribed. During each focus group, a scribe wrote out keywords and responses from participants while the moderator continued to engage participants in further discussion. Authors reviewed the notes and transcripts to identify and categorize common themes among responses.

Results

Survey of Environmental Health Specialists

Johnson County EHS completed six surveys, for a response rate of 100%. There were four male and two female respondents. All EHS had a 4-year college degree or beyond and were ServSafe certified. The respondents had served as Johnson County EHS for a length of time that ranged from 1 to more than 10 years. Of the six respondents, one was a certified food safety specialist, and five were registered EHS with two certifications provided through the National Environmental Health Association.

The majority (60%) of the EHS believed the services they provide to be effective. Overall, EHS were satisfied with their relationships with foodservice establishments, although the great majority of EHS agreed that improvements were needed in the following areas:

- Effective enforcement actions in response to food violations;
- Ability to influence decisions that affect job performance (unclear);
- Ability to provide training opportunities to foodservice establishments.

Four EHS (67%) also indicated that they either "disagreed" or "strongly disagreed" with the following statements: "Establishments do not face any barriers that would prevent compliance," and "There is not much more that we can do to ensure compliance."

Focus Groups with Restaurateurs/Foodservice Workers

Each restaurateur/foodservice worker focus group was comprised of four to 11 participants, for 21 participants. Feedback that emerged from the focus group sessions included perceived positives and negatives of the current inspection process, satisfaction with educational training and materials, barriers within the food industry that affect food safety, satisfaction with regulatory and compliance actions, motivating factors for food safety and suggestions for improving the inspection process and fostering partnerships between EHS and the food industry.

- *Positives of the inspection process.* EHS were perceived by many restaurateurs and foodservice workers as being well-prepared, responsible, professional and willing to provide information and address questions. The inspection process was viewed as beneficial because EHS were consistent in their methods. Additionally, inspection reports issued by EHS were viewed as helpful, since they allowed restaurateurs to focus on problem areas, thereby allowing them the opportunity to improve.
- *Negatives of the inspection process.* Some participants provided contradictory information by expressing that EHS lacked professionalism and were neither consistent nor helpful in suggesting solutions to problems. In addition, some participants reported frustration in dealing with different inspectors from the same agency, since this inconsistency did not allow them the opportunity to build rapport with a specific inspector. Finally, a significant number of participants indicated they were not well informed about services provided by EHS.
- *Educational training and materials.* Informational handouts and food safety booklets, provided in English and Spanish, were viewed as being highly effective by focus group participants and were frequently utilized for training purposes. Materials written in Spanish were considered very useful when training Latino workers with limited English-language skills.
- *Barriers within the food industry that affect food safety.* Participants cited several barriers that hinder their ability to comply with food codes and maintain food safety: language, high employee turnover rates, lack of education, lack of current information regarding health regulations and failure of EHS to notify them concerning such changes.
- *Regulatory and compliance actions.* Participants indicated that restaurateurs want to be held accountable for violations in their restaurants. However, they desired that the process be fair

1. What do you like about the service that we provide?
2. What do you dislike about the service that we provide?
3. What suggestions do you have to improve our services?
4. What do you think about the training/educational tools available (i.e., handouts, signage, focus on food safety booklets, food safety disks, food safety class, etc.)?
5. Of the materials we just discussed, which ones do you pay attention to and use more often? Why?
6. Which ones do you not use and why?
7. Are there any barriers within your restaurant that affect customer service or food quality?
8. What barriers do you face as foodservice workers that may affect your efforts to comply with food code regulations?
9. What regulatory and compliance actions do you feel are reasonable when food violations exist?
10. What would motivate you to stay in compliance and be proactive about food safety?
11. Do you feel like you can call the health department with any problems, questions or concerns?
12. How do you view the inspection process (negative/positive)?
13. How can we build a better relationship/create a positive partnership so that the public continues to enjoy dining out safely?

Table 1: Focus Group Questions

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and just. For example, participants welcomed the opportunity to discuss violations with EHS and explain their knowledge of health codes. Through such a cooperative process, they hoped to avoid fines and disciplinary actions for infrequent, accidental violations. Furthermore, participants expressed a desire that EHS be understanding and constructive in the inspection process. They stated that fines are hard on struggling restaurants and are not necessarily constructive. Finally, participants stated a need for more warnings, teaching and coaching for establishments with violations.

- *Factors motivating food safety.* Participants reported being motivated by the desire to serve safe food. The threat of citation or closure due to violations was only a secondary motivator. Restaurateurs expressed that they strive to deliver the best service possible, and that food safety, as opposed to avoiding citations, is the most important reason to comply with food codes.
- *Inspection process.* Participants indicated that email is the most effective method of communication, providing them with up-to-date information regarding changes in food code regulations, changes in the inspection process, classes and training offered by the health department and so forth. They reported that email also is useful for allowing them to communicate openly with EHS outside of the inspection process. They also showed strong interest in increased frequency of inspections as well as announced or courtesy inspections, which they claimed would help their staffs feel more at ease with EHS. Participants indicated the need for training videos that utilize blatantly unpleasant visuals, stating that such images are difficult to forget and serve as constant reminders regarding the importance of food safety.
- *Fostering partnerships between EHS and foodservice workers.* Constant communication with EHS through emails, courtesy inspections or drop-ins were among methods suggested for creating positive partnerships between restaurants and EHS. Participants felt EHS need to be more available by attending weekly or monthly staff meetings at restaurants and setting up training workshops at restaurants. In addition, public education from Johnson County EHS was recommended to address misconceptions about the restaurant industry. For example, participants felt that the public held misconceptions regarding food code regulations, violations and causes of FBI. These misconceptions tend to be negative, according to participants, and cause the public to become wary of their restaurants. Participants felt that violation postings on the state health department's Web site lead to false negative assumptions about their restaurants. Many felt this Web site should only list repeat violators.

*"Restaurateurs expressed that they **strive** to deliver the best **service** possible, and that food safety, as opposed to avoiding citations, is the **most** important reason to **comply** with food codes."*

Discussion and Implications

Results of this study indicate a great need for emphasis on training and education of restaurateurs and foodservice personnel, better communication and dissemination of up-to-date information between restaurateurs and EHS and the implementation of revised county-level inspection policies. The contradictory opinions expressed about EHS–that they were professional, communicative and knowledgeable, as well as unprofessional and inconsistent–could indicate respect for the EHS in general, but difficult specific encounters with inspectors, or perhaps a belief that EHS have knowledge regarding food safety that they are not sharing with the food industry.

Currently, before being employed, foodservice workers in Johnson County are not required to undergo food safety training. The lack of food safety knowledge, coupled with factors such as language barriers, improper food handling practices and high turnover rates, only adds to the challenge of getting food workers to implement behavioral changes. JCED–and other county-level food inspection agencies across the nation–need to respond to the realities of the foodservice workforce by developing more appropriate education and training programs for foodservice workers.

It is also important that local agencies focus on building relationships that foster trust and understanding through effective communication and constant education. As of 2008, Johnson County EHS offer food safety training classes to foodservice workers once every quarter. To be effective, the county will need to increase the number of classes offered and provide varying times for those classes, which will allow the flexibility and accessibility needed to accommodate the needs of different restaurateurs. Furthermore, these classes should be opened to the public so that consumers can be educated along with foodservice workers. Consumers, too, need to understand the importance of food safety, the effectiveness of handwashing in reducing the spread of disease, how to identify food code violations and when to call the health department for intervention.

Because the sample size for this study was relatively small, it may not be representative of Johnson County as a whole. In addition, the majority of the focus group participants held high-level management positions within their prospective restaurants. Therefore, responses to questions such as barriers faced within restaurants may have been guarded. In addition, this project did not include non-English speaking restaurateurs. While the researchers acknowledge these limitations, the results can still be useful in guiding future studies about the vital role of partnerships within the food industry.

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The restaurant inspection process should be advantageous for both the EHS and restaurateur, who both share the goal of serving safe food to consumers. The results of this study indicate that improvements can be made to increase positive interactions between restaurateurs and EHS as they evaluate food safety practices. This study may prove useful for other communities who wish to evaluate local-level food safety relationships. ■

Acknowledgments

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Pathogenic Non-O157 *Escherichia coli*

Food processors face an ever-evolving set of challenges in their endeavors to ensure the safety and quality of their products. Until recently, efforts to control and eliminate pathogenic bacteria from food have primarily focused on well-known organisms such as *Salmonella, Listeria* and *Escherichia coli* O157:H7. However, there is growing interest in the potential public health risk associated with a broader group of *E. coli* commonly referred to as "the top six non-O157 STEC" or "Top STEC."



What Are STEC/VTEC/EHEC?

One aspect that often causes confusion is the variety of terms and acronyms used to refer to this group of organisms. Three of the most commonly used terms are Shiga toxigenic *E. coli* (STEC), Vero toxigenic *E. coli* (VTEC) and Enterohemorrhagic *E. coli* (EHEC).

STEC/VTEC refers to those strains of *E. coli* that produce at least one member of a class of potent cytotoxins called Shiga toxin. Because the terms Shiga toxin and Vero toxin both refer to the same group of toxins, STEC and VTEC can be used interchangeably.

EHEC is a subset of the STEC group that has been implicated in the clinical illness hemorrhagic colitis (HC) or the potentially fatal hemolytic uremic syndrome (HUS).[1]

E. coli are also categorized based on their serotype, defined by the O antigen determined by the polysaccharide portion of cell wall lipopolysaccharide (LPS) and the H antigen due to flagella protein. The most prevalent and widely recognized EHEC serotype is *E. coli* O157:H7.

Which Organisms Are Significant?

While the literature suggests that there are 100 to 250 different serotypes of STEC, not all serotypes are necessarily pathogenic. Most surveillance studies of clinical isolates report that the following six STEC O serogroups, in addition to O157, represent the greatest public health risk: O26, O111, O102, O121, O145 and O45.[2,3] Karmali et al. present a classification system based on the specific serotype's prevalence and association with either HC or HUS (Table 1).

Type	Serotype	Incidence	Frequency	Causes Severe Disease
A	O157:H7, O157:NM	high	common	yes
B	O26:H11, O111:NM, O103:H2, O121:H19, O145:NM	moderate	uncommon	yes
C	O91:H21, O104:H21	low	rare	yes
D	multiple	low	rare	no
E	multiple	non-human	NA*	NA

Table 1: Seropathotype Classification of STEC[4] *NA, not applicable

Most experts agree that the pathogenicity of a specific strain of *E. coli* is determined by the presence of two specific genetic targets, the *eae* gene, responsible for the formation of an attachment and effacing lesion on the host's intestinal epithelial cells, and one of the two *stx* genes (stx_1 and stx_2), responsible for production of the cytotoxin.

Impact on Industry

At the International Association of Food Protection annual meeting in August, the USDA Food Safety and Inspection Service provided an overview of their current method under development for detection of the top six non-O157 STEC serogroups from beef trim and ground beef. In summary, the method involves an overnight enrichment followed by analysis via multiplex polymerase chain reaction (PCR) for the presence of both *eae* and the *stx* genes. Positive enrichments are subsequently screened via a series of reactions for the presence of one of the top six O-serogroups (O26, 0111, 0102, 0121, 0145 and O45). Enrichments found to be positive for *eae*, *stx* and one of the top six O-serogroups will proceed to confirmation via immunomagnetic separation (IMS) and selective agar plating. Typical colonies will be struck for isolation and purification and subsequently tested via agglutination procedures to establish their O-serotype. USDA and beef industry representatives agreed that faster, more streamlined methods would be required for industry to implement an effective system for detection of these organisms.

Assurance GDS® for Top STEC

As a leader in pathogen detection, BioControl Systems has developed a new method to satisfy industry's need for an easy, fast and accurate method for the detection of the top six non-O157 STEC. Using the proven Assurance GDS platform and enrichment media common to both the *E. coli* O157:H7 and Shiga toxin gene assays, the method consists of a simple and innovative IMS-based sample preparation procedure that helps narrow the field to the six target O-serogroups prior to molecular analysis with the Assurance GDS® Rotor-Gene™. The instrument's unique rotary design and the probe-based detection system combine to provide results in less than 12 hours including enrichment. With assays for *E. coli* O157:H7, Shiga toxin genes, Top STEC, *Salmonella*, *Listeria* spp., *Listeria monocytogenes* and *Cronobacter* (*Enterobacter sakazakii*), this pathogen detection system is ideally suited to help food processors to meet their food safety objectives. For more information about the Assurance GDS® System, please contact BioControl Systems at www.biocontrolsys.com.

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Detecting *Salmonella* Enteritidis in Shell Eggs



Eggs are a staple in most Americans' diets. On average, Americans consume 220 million eggs daily. This summer, the U.S. experienced one of the largest recalls involving eggs potentially contaminated with *Salmonella* Enteritidis (SE), implicating over 500 million eggs and linked to more than 2,000 reported illnesses. SE is the second most commonly human-isolated *Salmonella* serotype according to the Centers for Disease Control and Prevention, responsible for over 200,000 illnesses a year in the U.S. About 64% of those illnesses are attributed to eggs or egg-containing products.

Also this summer, the U.S. Food and Drug Administration (FDA) enacted a new Final Rule entitled "Prevention of *Salmonella* Enteritidis in Shell Eggs During Production, Storage and Transportation" (74 FR 33030). The Rule mandates testing of the layer house environment for SE. If SE is detected, eggs are then screened to ensure no contaminated eggs reach consumers. Despite the recent regulation governing testing and control of SE in eggs, it remains a threat to consumer product safety. Testing for SE will need to be made easy-to-do and cost-effective, with rapid test kits readily available to the market, which today is simultaneously facing a new regulation and a costly recall.

How Does *Salmonella* Enteritidis Contaminate the Egg?

SE egg contamination begins in the layer house environment. It is introduced into the house by means of infected pullets or by vectors such as flies and rodents. Once inside the house, the hens ingest SE through contaminated insects or feed. The pathogen begins to multiply in the organs of the hen, such as the ovaries. SE is then available to potentially contaminate developing eggs before they are laid.

FDA Rule Focuses on SE in the Layer House

If contamination of the house is found through routine environmental monitoring, it can be eliminated or reduced, thus halting or reducing SE exposure to the hen and ultimately to the egg. The new FDA Final Rule focuses on monitoring the layer house for SE and keeping the house SE-free.

The Challenge: FDA BAM Method for Detecting SE in Environmental and Egg Samples

Part of the Final Rule includes a proposed method to test environmental and egg samples for SE. This method requires multiple transfer steps, different media and agar to prepare and store, two different incubators, trained microbiologists and at least 3–7 days for a negative result. Egg producers should not be asked to compromise on SE testing. Rather, they should look for alternative methods where they can get the accuracy, ease-of-use, training efficiencies, faster time-to-result and reduced overall testing costs they need to provide safe eggs and a sound business.

The Solution: RapidChek® SELECT™ *Salmonella* Enteritidis

The RapidChek SELECT SE test system is a breakthrough in *Salmonella* testing for the industry, offering one of the first sero-specific rapid assays. This technology was developed with direct input from egg producers who experienced difficulty complying with the testing demands of the new FDA Final Rule. The system generates exceptionally accurate results in the most challenging samples in a highly cost-effective and timely manner.

This system delivers results for environmental samples 1 day faster than the FDA BAM method and with increased sensitivity and accuracy. The system also delivers results for egg samples 5 days faster than the FDA BAM method. These benefits of time and accuracy allow egg producers to identify SE in the environment before it contaminates eggs, thus ensuring safer eggs and reducing the chances of a costly egg recall. This ability to screen for SE quickly and accurately is especially relevant today given the recent egg recalls.

Easy, Cost-effective SE Testing

The RapidChek SELECT SE ensures easy and cost-effective compliance with the new FDA Final Rule. Labs that ran this system side-by-side with competitive methods have realized a measurable reduction in hands-on time, time-to-result and overall testing costs. Moreover, there are no up-front expenses for automated equipment, annual maintenance fees or contracts to sign.

Reasons to Choose RapidChek SELECT *Salmonella* Enteritidis

1. **Accurate Results.** Very low levels of false positives and negatives provide minimal disruption to daily operations.
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3. **Simple.** Continual training of staff on complex traditional and culture methods is exhausting, and it drains a company's resources. The system's simplicity will reduce the number of potential errors.
4. **Fast Time to Result.** Users must choose a method that will give results in a timely fashion. The system reduces the time-to-result by days.
5. **Provides Valuable Information.** The system provides an early indicator of potential environmental SE contamination before the contamination becomes transferred to the egg.

Conclusion

Using an accurate, easy-to-use method to test environmental and, if required, egg pool samples, will make transition to and maintenance of complying with the FDA Final Rule easy. It will also help egg producers advance the safety of eggs while minimizing expenses but not disrupting everyday operations.

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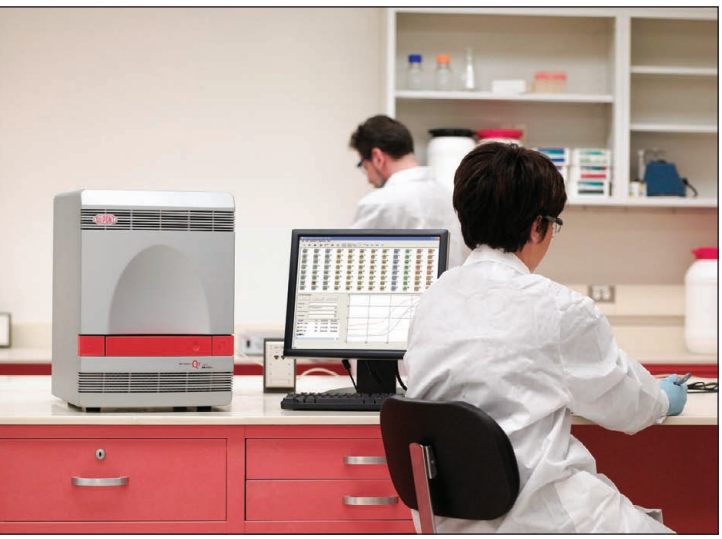
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DuPont Qualicon was the first company to apply polymerase chain reacion (PCR) technology to food testing with rapid, DNA-based assays for *Salmonella, E. coli* O157:H7 and *Listeria monocytogenes*. Our use of automated PCR processing with tableted rather than liquid reagents created a dramatic increase in speed and consistency—helping to usher in a new era of easy-to-use testing methodology.

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For years, leading food companies and government testing labs around the world have relied on the genetics-based BAX® System to quickly and accurately detect pathogens such as *Salmonella, E. coli O157:H7, Listeria* spp., *L. monocytogenes, Enterobacter sakazakii, Campylobacter, Staphylococcus aureus* and more. In fact, government testing agencies in the United States, Canada, Brazil, Japan and other parts of the world have adopted or validated the BAX® System as an approved testing method to protect their food supply and their citizens.

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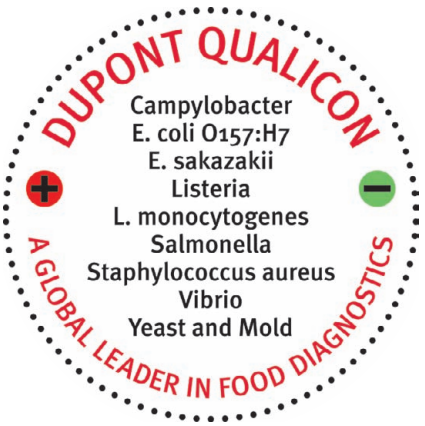
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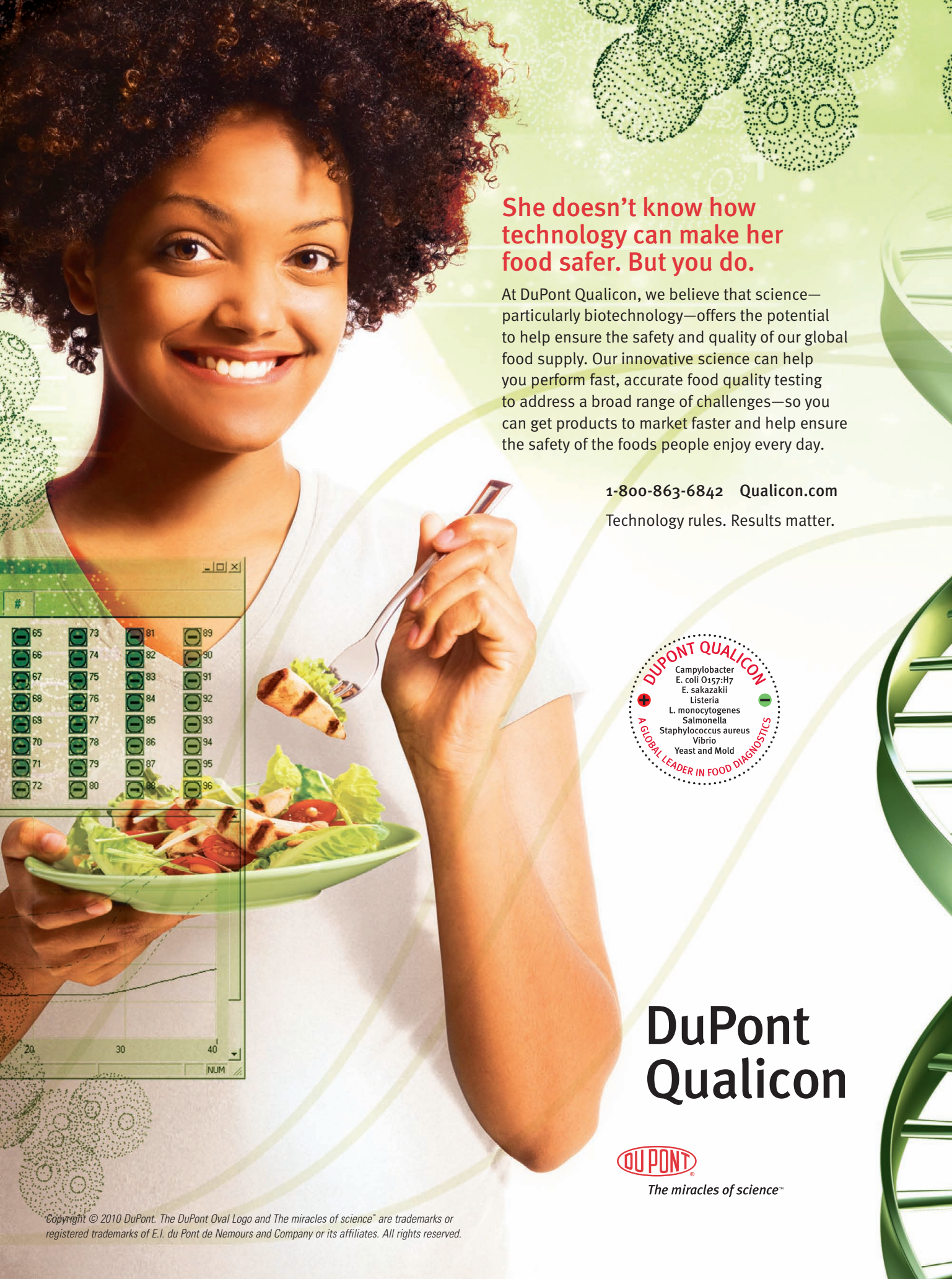
Our recent incorporation of highly sensitive and adaptable Scorpions® technology enables us to develop rapid multiplex assays for detecting microorganisms that are often difficult to find. With cutting-edge technology like this, we are developing increasingly faster, more sensitive tests for pathogens and spoilage organisms. In fact, we recently entered into a collaborative agreement with the USDA ARS to develop a new test for non-O157 serotypes of *Shiga* toxin-producing *E. coli* (STEC) that will be based on the BAX® System.

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High-throughput PCR Provides Real-time Solutions



Foodborne bacterial contamination is estimated to cause about 76 million illnesses per year in the United States alone. In a report from the United States Department of Agriculture Economic Research Service, foodborne illnesses account for about 1 of every 100 hospitalizations and 1 of every 500 deaths in the US. The most common bacterial pathogens attributed to outbreaks are *Salmonella, Listeria monocytogenes, Escherichia coli* O157:H7 and *Campylobacter*. According to a Centers for Disease Control and Prevention report tracking foodborne illnesses in 2007, of all the outbreaks attributed to a single food, 17% were from poultry, 16% from beef and 14% from leafy vegetables. Other food commodities have been plagued by massive recalls due to contamination including peanut butter, tomatoes, spices and, more recently, eggs.

The iQ-Check™ real-time polymerase chain reaction (PCR) system from Bio-Rad Laboratories was designed specifically with the needs of users in mind with kits available for *Salmonella, L. monocytogenes, Listeria* spp., *E. coli* O157:H7 and *Campylobacter*. The use of highly specific probes and primers results in excellent sensitivity and specificity, validated by AOAC. With a high-throughput extraction, all pathogens can be tested at the same time, making life for the laboratory a little bit easier. Two instrument platforms are available for all sized labs. The 96-well, 5 color CFX96™ system is designed for high-throughout analysis while the 48-well, 2 color MiniOpticon™ is perfect for smaller labs.

In Need of a Better Method

Chestnut Labs (Springfield, MO) provides clients with food safety testing, auditing, training, consultation and research including test kit validations and shelf-life studies. In operation for more than 20 years, the lab is recognized for its superior customer service and ability to be a value-added business partner for its clients. Chestnut Labs operates under the ISO 17025 principles and is committed to providing clients with a commitment to quality and constant improvement.

Michael Clark, laboratory director at Chestnut Labs, mentions that cost and turnaround time are very important to their customers. The company needed a fast and dependable real-time PCR platform where multiple pathogens could be tested simultaneously. The laboratory needed a protocol that was user friendly and capable of high-throughput analysis to eliminate the usual bottleneck areas common of real-time PCR tests. The iQ-Check method met those needs. With the combination of the high-throughput extraction protocol, the CFX96 real-time PCR detection system and the CFX Manager Software, Chestnut Labs was able to provide their customers with reliable, next-day results without passing on an additional cost.

When asked what the advantages of this product were for their use, Clark added, “The use of a deep-well microplate allows for the high-throughput processing of 96 samples at a time. The deep-well protocol has eliminated the multiple heating, shaking and lysis steps associated with most commercial PCR kits by consolidating the steps into one. Using the deep-well plate protocol allows multichannel pipetting for most steps of PCR preparation, saving time and reducing cross-contamination. The software is simple to use and interpret, and the option to email results with an attached data file helps reduce time. Faster PCR times increase productivity. The use of non-proprietary enrichment broths helps us reduce the overall cost per sample.” Some additional benefits of the system include no special sample preparation or post enrichment re-grow step, the inclusion of an internal control to validate the PCR runs as well as a small footprint that does not take up much bench space.

Standard methods, such as the U.S. Food and Drug Administration’s Bacteriological Analytical Manual (BAM) testing method, which involves a pre-enrichment step followed by a second selective enrichment step and plating (which can include secondary plating), takes 72–96 hours (3–4 days), which depends on the food sample being analyzed and must be followed by biochemical/serological confirmation, increasing the time to results to up to 5 days minimum. The iQ-Check *Listeria* spp. and *L. monocytogenes* kits only require a 24 hour enrichment. The *Salmonella* test requires a 20 hour enrichment, and the *E. coli* O157:H7 test can be processed after an 8 hour enrichment.

Chestnut Labs tests for all significant food pathogens and indicator organisms to provide the highest service for their clients. For them, Bio-Rad’s iQ-Check kits have increased productivity through faster and simpler sample preparation, faster PCR run times and the capability of running multiple pathogens at the same time. Their customers also benefit by receiving results faster, which reduces their product hold time.

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Top-performing food microbiology laboratories realize the importance of effective proficiency testing (PT) programs. Safety, reputation and accreditation depend on it. Food microbiology laboratories turn to PT providers to assess their competency and identify areas in need of improvement. Successful performance in an external PT program is a key indicator of high laboratory quality. Microbial strains with confirmed identity, viability and purity, backed by meticulous laboratory procedures that minimize subculturing, are important components of proficiency testing programs. And, they are important to ATCC.



Since 1925, ATCC has set the standard for authenticating and distributing biological materials for research and testing in the life sciences. ATCC's mission is to acquire, authenticate, preserve and distribute biological materials, information, intellectual property and standards for the advancement, validation and application of scientific knowledge.

ATCC Proficiency Standard® Program

ATCC established the Proficiency Standard program to improve the laboratory PT system by raising the quality and consistency of the microorganisms and biological materials used in PT samples. In addition, the program improves laboratory safety by working with PT providers and manufacturers to qualify microorganisms for identity and biosafety level before being included in a PT panel. The program also provides traceability of the PT sample materials. Microorganisms are tested for confirmation of identity using a polyphasic approach that incorporates traditional biochemical tests, phenotypic testing and genotypic tests. Fully authenticated PT materials bring consistency and reliability to PT and allow results to be compared within a group of laboratories.

In the past, microorganisms used in proficiency panels have been reported to have been subjected to excessive subculturing, have had unknown pedigrees, have been misidentified, contaminated and may have been stored under variable conditions. These factors can degrade the quality of the PT programs and expose laboratory personnel to undue hazards.

"As a nonprofit company devoted to science and the public health, we take very seriously our responsibility to ensure the quality of the materials provided by ATCC," Raymond H. Cypess, DVM, Ph.D., ATCC President and CEO explained. "Microbiologists deserve to know with certainty that any materials they obtain for proficiency testing have been identified to the genus and species level using polyphasic testing that is performed in an ISO/IEC 17025:2005 accredited laboratory."

ATCC is ISO/IEC 17025:2005 accredited. ISO/IEC 17025:2005 is an international standard that specifies the general requirements for the competence of testing and calibration laboratories. The scope of the ATCC ISO/IEC 17025:2005 accreditation, which extends across a wide range of the organization's quality control testing, includes tests for biochemical identification, viability, titer, phenotypic identification and genotypic identification including sequencing and riboprinting.

Whether in PT, quality control testing or process validation, the source of the microbial strains used should be considered a vital factor in generating valid, accurate results. If you think the inclusion of any strains will do, you may want to think again. To identify microbial strains that are handled, stored and tested with the unparalleled expertise that comes from over 80 years of experience, look for the ATCC symbol of quality—the ATCC Proficiency Standard® program. A select group of commercial manufacturers and providers are licensed to provide microbial strains traceable to ATCC in their PT programs.

Program Users

- PT service providers select specific strains for use in their PT panels
- Manufacturers use strains from the ATCC Proficiency Standard Program to produce PT panels
- Laboratories use proficiency panels in their required and elective testing. Laboratories where PT is performed, include food, clinical and quality control laboratories

The following organizations are currently participants in the ATCC Proficiency Standard program:

- Accutest Laboratories, Inc.
- American Academy of Family Physicians (AAFP)
- American College of Physicians Services, Inc. (ACP)
- American Proficiency Institute (API)
- Centre Suisse de Controle de Qualite
- Cleveland Clinic
- College of American Pathologists (CAP)
- Kendle International, Inc.
- MicroBioLogics, Inc.
- R&D Systems, Inc.
- Remel, Inc.
- Wisconsin State Laboratory of Hygiene (WSLH)

Symbol of Quality

The ATCC Proficiency Standard program benefits both the public and private industry by helping to make PT as valid, accurate and safe as it can be. Don't take chances on the quality of the strains provided in your PT program. Be sure your PT provider is using microbial strains traceable to the ATCC Proficiency Standard program in their proficiency panels.

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We've got your number.



And it's exactly what you're looking for.

Ever find yourself wondering about the true identity of your proficiency testing material? We can put your suspicions to rest.

The ATCC® Proficiency Standard® Program ensures that proficiency testing (PT) panels are consistent, safe, reliable and traceable to their source. We know what's in every vial of proficiency testing material because we use a battery of polyphasic tests to characterize each lot.

Save the mysteries for fiction writers. Check out the ATCC Proficiency Standard Program at **www.atcc.org.** Click on "ATCC Proficiency Standards" from the "Standards" drop down menu.

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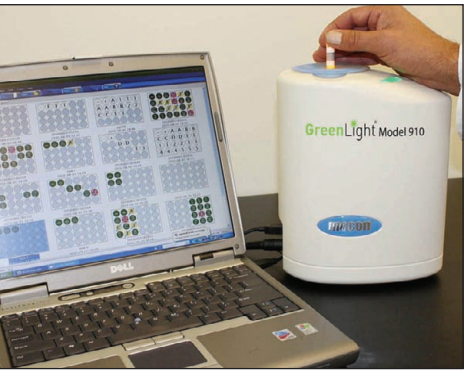
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Breakthrough Same-day Bacterial Analysis for Food Products

An increasing appreciation for the importance of food and microbiological safety has resulted in a demand for a rapid, high-throughput method for total viable count (TVC) quantification to deal with the increasing numbers of samples that require testing.



The industry standard for TVC determination (ISO:4833:2033), also known as aerobic plate count (APC), is widely used but presents users with some very significant drawbacks. The method is both material and labor intensive, requiring the preparation and analysis of multiple agar plates per sample. More importantly, the method is slow, with 48–72 hours typically required for a definitive result.

MOCON, in association with Luxcel Biosciences, has addressed these limitations with the development of the GreenLight™ 900 Series, a breakthrough, low-cost system with reduced labor and material, providing microbiological analysis in just hours.

Rapid determination of TVC/APC levels has an immediate impact on your business in the following ways:

- Measures microbiology quality immediately after delivery
- Fast decision-making toward suppliers
- Standardizes internal microbiology quality control for goods received
- Immediate grading of incoming products
- Rapid hygiene indicator of products
- Contributes to competitive advantage
- Constant monitoring of production process (hygiene)

This process results in safer foods for consumers.

How Does It Work? (The Really Simple Explanation)

This sensor technology is based on oxygen sensing. As microbes grow, they consume O_2. The system measures bacterial O_2 consumption and equates that to viable microbial load (live bacteria).

Accuracy

A strong correlation is observed between the GreenLight and the ISO:4833:2003 methods for the assessment of bacterial contamination, for example, in ground beef samples; Pearsons correlation coefficient = 0.961.

Available in Two Models

- Model 960 (AOAC approved), a 96 micotiter plate-based assay that provides rapid high throughput.
- Model 910 (AOAC approval pending), a vial-based system providing low to medium throughput.

Simple to Operate

The system does not require laboratory trained technicians to operate it.

Model 960 is a simple 'mix and measure' assay 96-well plate system. Using food homogenates, prepared as for traditional TVC/APC testing (with no further dilutions necessary) (ISO:4833:2033), probe, sample and oil are added in sequence and resultant aerobic TVC/APC values quantified using an appropriate calibration. The plate is measured kinetically on a fluorescence plate reader.

Model 910 uses the same preparation (no further dilution is necessary) with the samples being placed in a vial that already contains the sensor. Readings are taken by placing the vial into the sample receptor slot of the instrument, and results are recorded by the software. Each vial is supplied with a unique bar code that is automatically read during sensing, ensuring that results are recorded against the correct sample.

Variety of Testing Protocols

Operators have the option of a variety of testing protocols:

- Simple two-point pass/fail
- Multipoint mode – gives pass/fail and semi-quantitative TVC/APC (CFU/g) level
- Continuous mode – gives pass/fail and absolute TVC/APC (CFU/g) level

Wide Contamination Range

This system can measure aerobic bacterial respiration across a wide contamination range 10^0–10^8 CFU/g.

Same-day Results (including sample preparation time and incubation)

In comparison to the conventional approach, the GreenLight 900 series provides a much improved 'time-to-result' with less than or equal to 10^3 CFU/g detectable in approximately 12 hours compared to the 49 hours required by the standard method (≥10^8 CFU/g are detectable within 1 hour).

Saves Money

The system reduces preparation time with no further dilutions necessary, which also reduces media cost. It is less labor intensive, and there is no need to be an engineer or scientist to conduct tests. It reduces incubator space: three plates (288 tests) can be stacked in the same area occupied by six agar plates.

Standardizes Procedures

Results are recorded automatically within the software, removing the need for difficult and tedious counting and subjective observation of colony numbers.

Learn More

To obtain a copy of the GreenLight White Paper or for more information on the specific models, contact MOCON at info@mocon.com or phone us at 763-493-6370 or www.mocon.com/foodsafety.php.

www.mocon.com/foodsafety.php

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BREAK THROUGH

Same-day bacteria analysis for meat and food products

Food Safety

~~72 hours~~
~~48 hours~~

5 hours

SAVE TIME
SAVE MONEY
REDUCE RISK

Low-cost system providing microbiological analysis in hours, including sample preparations and incubation time.

GreenLight™ 900 SERIES



Two Models available.



The Model 960 is AOAC approved, and the Model 910 is pending approval.

Fast determination of total viable counts/aerobic plate counts (TVCs/APCs) levels has an immediate impact on your business:

- **Measure microbiology quality immediately after delivery**
- **Fast decision making toward suppliers**
- **Standardise internal microbiology quality control for goods received**
- **Immediate grading of incoming products**
- **Rapid hygiene indicator of products**
- **Contributes to competitive advantage**
- **Constant monitoring of production process (hygiene)**

...this results in safer foods for consumers.

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Product Tracing
Legislation versus Reality

By Jennifer C. McEntire, Ph.D.

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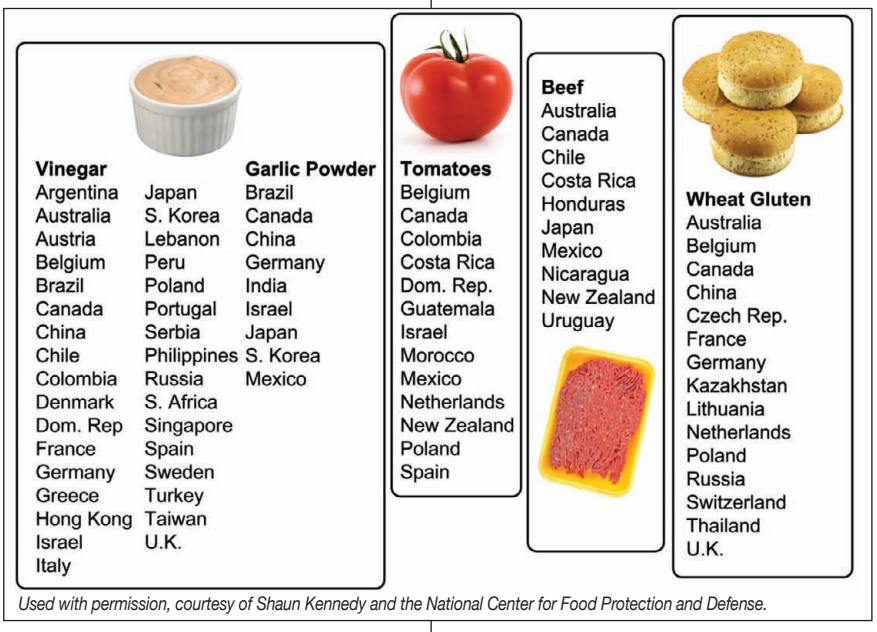
in Food Systems:

It is easy to justify procrastination when you are in Washington, D.C., since you know that Congress won't pass legislation until after your article is nearly complete. By all accounts, food safety legislation should have passed by now, and yet other major societal issues keep taking a front seat.

Since the Institute of Food Technologists (IFT) published our reports on product tracing in November 2009, the most commonly asked question has been, "What's next? What will the U.S. Food and Drug Administration (FDA) do?" At first, it was easy to refocus the question on the FDA (and the U.S. Department of Agriculture) since a public meeting was scheduled for December 2009 and a comment period was open until March 2010. The FDA was collecting input before deciding what to do. More recently, the question is refocused to Congress: until Congress decides what to do, the FDA may not act. However, as time has passed and S510 and HR 2749 have been dissected, there seems to be a general sense of where food safety legislation—at least in terms of product tracing requirements—might wind up.

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Product tracing is the ability to trace potentially contaminated product, the consumption of which may cause an adverse health impact, through the supply chain. There is some debate whether product tracing is related to food safety. It is. When a potentially contaminated product is in the supply chain, and perhaps in the marketplace, there is the potential for consumers to become ill–a food safety issue. Rapid, accurate product tracing allows that product to be removed from distribution, protecting public health. Some in the food safety community argue that product tracing is strictly reactive, since it isn't activated until after a contamination event has occurred. That's not necessarily true. The ability to trace back and identify points of convergence can help identify the root cause of an issue and, hopefully, put controls in place to stop that type of issue from occurring again. A good traceback can help prevent a future event.



Used with permission, courtesy of Shaun Kennedy and the National Center for Food Protection and Defense.

Figure 1: Globalizing the Cheeseburger

Outbreaks Drive Recognition of Issues

Too many outbreaks, each with individual nuances, have exemplified the inability to trace products *throughout a supply chain*. Many firms report that they are able to trace products. When pressed for details, it might be revealed that they may have very good internal controls or may keep great records at receiving and shipping. This doesn't mean that their supply chain partners have these systems in place. The supply chain is only as strong as its weakest link.

Hopefully, product tracing systems and practices will continue to improve so that the Peanut Corporation of America incident will remain the prime example of product tracing gone wrong. If all firms in the longest supply chain used the maximum 24 hours to identify one step forward and one step back (as required by the Bioterrorism Act of 2002), all affected product should have been identified within days, perhaps weeks. Instead, for months after the problem was identified, product recalls continued to be announced, culminating in over 360 firms issuing recalls of nearly 4,000 products.

In contrast, the infamous tomato/pepper outbreak might be viewed as product tracing gone theoretically right (with the epidemiological investigation going wrong). Although the recordkeeping practices of the produce industry were blamed for the inability to identify the point of convergence of contaminated tomatoes, and certainly, paper records slow things down, the fact that common points along the supply chains were not found could have suggested that tomatoes were not the culprit.

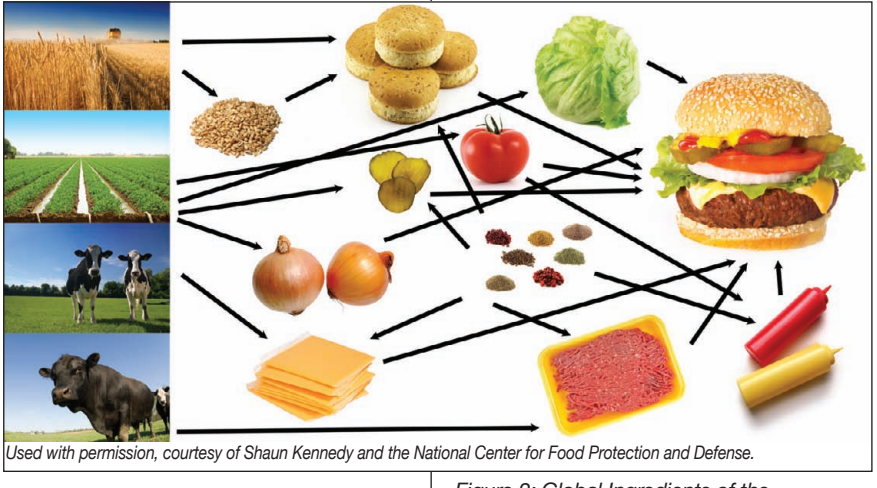

Used with permission, courtesy of Shaun Kennedy and the National Center for Food Protection and Defense.

Figure 2: Global Ingredients of the Cheeseburger

COOL Is Not Product Tracing

Still, these high-profile cases gave American consumers a glimpse into the complexity of the food supply chain and left them wondering where their food actually comes from. When IFT conducted a study of product tracing in food systems, done under contract with the FDA in 2008–2009, we spoke to 58 food companies along several points in the supply chain for the produce, ingredient and processed food industries. Country of origin labeling (COOL), while intended as a marketing tool, was cited by many firms as providing consumers with information about product origins. The loopholes associated with COOL won't be discussed here, except to say that COOL does not provide product tracing. As mentioned previously, product tracing is a requirement of the system, with visibility needed at each point in the supply chain. Simply knowing the country of origin is insufficient, and for some products, the complexity of the supply chain is such that the list of supplying countries is long. As illustrated in Figures 1

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Food Defense.

Don't Gamble with It!



Effective product protection requires risk identification and risk management

Identifying Risk
Do you know the specific risks for your process, facility and supply chain? Have you taken the time to carefully evaluate them, or are you relying on generic standards and checklists? Does your customer really understand your business well enough to identify what you should be concerned about? Are you tired of conflicting requirements from third-party audits? There is a better way.

Managing Risk
Effective risk management does not involve one size fits all fixes. Are you relying on audits to manage your risks? What are the audits really telling you? Compliance with generic standards will not protect your product. Instead, invest only in the improvements needed to minimize your real risks to protect both your product and your bottom line.

The Problem:
Current food defense practice is too generic. Compliance with general guidelines could be costly and will not protect your product.

The Solution:
Focused assessments that identify real concerns and cost-effective, targeted solutions.

Don't gamble with food defense! Contact SAIC Food Defense Solutions.

For more information about how SAIC can help protect your product supply chain, please visit us at **www.saic.com/food-safety**

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and 2, even something as American as a cheeseburger can have ingredients sourced from around the world.

Current Requirements

Different parts of the food industry are subject to different laws that are often administered by different government agencies. However, the 2002 Bioterrorism Act provided a major recordkeeping requirement that most equate with product tracing. The Act requires what is commonly referred to as "one up/one back" recordkeeping. Specifically, recipients of a product are required to record from whom they received a product, and upon shipping, they must document to whom they sent product. The assumption that the requirements of the Act provide product tracing is wrong for at least three reasons. First, some are exempt. Exemptions at the ends of the supply chain, such as the farm and retail, are not ideal, but with the one up/one back system, the primary recipient of a product from a farm should know where the product came from, making a matching record at the farm level redundant. The greater issue with the exemptions is when they apply to those in the middle of the supply chain, such as brokers, who play a major role in the food production system. A lack of records results in a break in the chain. The second issue with the Act is the inadequacy of the data required to allow for product tracing. Lot numbers are critical pieces of information to distinguish product. Language in the Act reads that lot numbers shall be recorded "if available," and this provides a substantial amount of wiggle room. In fact, in the IFT study, a major barrier to improving product tracing was that suppliers did not provide the necessary information. Lastly, had the Act been written to provide perfect product tracing, requiring all in the supply chain–at least the part in the U.S.–to keep the appropriate information, the FDA could not impose these requirements around the globe, nor could the FDA enforce them. Everyone involved in food understands the tangled web of food production and procurement, and the concept of worldwide food tracing, though necessary, seems daunting.

Pending Legislation

At several points over the past few years, a la carte product tracing bills have been proposed by various members of the U.S. Congress, and are included in Table 1. It now appears that the greatest change to product tracing requirements will result from the passage of some form of the Food Safety Modernization Act (S510, which has not yet passed the full Senate as of this writing, and HR 2749, which passed the full House in the Summer of 2009).

Tracing in Senate Bill S510

The product tracing requirements outlined in the current version of S510 give the Secretary of the Department of Health and Human Services (HHS), who oversees the FDA, a great deal of flexibility regarding the implementation of product tracing systems. It must be noted that the Senate bill has not yet passed the full Senate, with a manager's amendment released in August 2010. Despite the overall general language on product tracing, there are two specific elements that may decrease the ability to trace food: 1) the legislation would not require product tracking to the case level and 2) additional recordkeeping requirements would be imposed for "high-risk foods." Part of the definition of "high-risk foods" pertains to the processing steps that reduce likelihood of contamination. Clearly, lack of compliance with Good Manufacturing Practices is not accounted for, and many foods involved in recent outbreaks would not have been designated "high-risk."

Tracing in House Bill 2749

In contrast to the Senate bill, the House bill, which has already made its way through the full House, provides much more detail on product tracing requirements. It would authorize the Secretary of HHS to "(i) identify technologies and methodologies for tracing the distribution history of a food that is, or may be, used by members of different sectors of the food industry, including technologies and methodologies to enable each person who produces, manufactures, processes, packs, transports or holds a food to (I) maintain the full pedigree of the origin and previous dis-

Act Name	Bill Number	Summary
Trace Act of 2009	HR 814	Traceability system for all stages of manufacturing, processing, packaging and distribution
Food Safety Modernization Act	HR 875	National traceability system of 2009 that enables the Administrator to retrieve the history, use and location of an article of food through all stages of its production, processing and distribution
Food Safety Tracking	S425	Establish a national traceability Improvement Act system that enables the Administrator to retrieve the history, use and location of an article of food through all stages of its production, processing and distribution
FDA Food Safety Modernization Act	S510	Secretary (HHS) shall provide a report with recommendations for enhanced surveillance, outbreak response and traceability
E. coli Traceability and Eradication Act	HR 6024	Secretary (Ag) must trace contaminated beef samples to identify all sites of adulteration and contamination, including preparation, packaging and slaughtering establishments

Table 1: Recent U.S. Bills Addressing Product Tracing

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tribution history of the food; (II) link that history with the subsequent distribution of the food; (III) establish and maintain a system for tracing the food that is interoperable with the systems established and maintained by other such persons; and (IV) use a unique identifier for each facility owned or operated by such person for such purpose, as specified under section 1011 and (ii) to the extent practical, assess (I) the costs and benefits associated with the adoption and use of such technologies; (II) the feasibility of such technologies for different sectors of the food industry; and (III) whether such technologies are compatible with the requirements of this subsection." As a result, "the Secretary shall issue regulations establishing a tracing system that enables the Secretary to identify each person who grows, produces, manufactures, processes, packs, transports, holds or sells such food in as short a timeframe as practicable but no longer than 2 business days….The Secretary may include in the regulations establishing a tracing system (i) the establishment and maintenance of lot numbers; (ii) a standardized format for pedigree information; and (iii) the use of a common nomenclature for food." This bill also specifies that public meetings and pilot projects should be conducted.

Of particular concern is the authority of the HHS Secretary to perform studies on and standardize formats for pedigree. While the term pedigree is not defined in the bill, the concept seems extremely attractive: with a pedigree, you can see the entire history and path of a product at a glance. There is no need to do a laborious trace, since each handler of a product adds their name to the list as the product moves through the supply chain. In an industry where the barriers to entry are very low, resulting in numerous small operators (particularly in the world of blenders, repackers and the like), where price is a deciding factor in purchasing decisions, where rework is a fact of life and where substitutions are not uncommon, accurately handling information to provide a pedigree seems unlikely to be successful or economical in the near term. Currently, S510 does not explicitly require a full pedigree.

Forecasting the Future

No one knows what the final legislation on product tracing will look like. However, there has been speculation that some key elements of the House bill might win out.

Pilot Studies

It appears likely that the Secretary of HHS would be required to conduct some pilots, and the only argument heard from industry on this aspect is that more pilots should be conducted. It will be very difficult to capture the nuances and specific practices of each industry if only a few pilots are conducted. When IFT was contracted by the FDA to perform a mock traceback of the tomato supply chain, industry and trade associations argued that the simplicity of the tomato supply chain was not representative of the complexity of other produce supply chains. If the diagrams that the FDA shows illustrating the tomato supply chain are simple, I fear what complexity looks like! A pilot study of a complex processed food will surely face some challenges–primarily in the acquisition of so much data.

> "The supply chain is only as strong as its weakest link."

Industry, with support from trade associations, has begun making enhancements to the way products are traced in anticipation of pending legislation, and in response to the deficiencies illustrated by numerous outbreaks. Table 2 shows the vision for and objective of product tracing in various sectors of the food industry, the way products are currently identified and the way they might be identified moving forward. It appears that many industries are adopting the GS1 system of global standards. An overview of the types of standards that GS1 supports (e.g., standards for expressing data and transmitting data) can be found at www.gs1us.org for those in the U.S.

Culture Shifts

For tracebacks and trace-forwards to become more rapid, some parts of the food industry will need to change the way they record information, and in some cases, the way they view product. IFT found that some firms assigned identifiers to pallets, or in some cases even entire truckloads, making it very difficult to distinguish how the components of the pallet or truckload traveled through the supply chain. Additionally, the "first in, first out" inventory rotation system, relied upon to a great extent by some segments of the food industry, is wrought with exceptions, necessitating accurate recordkeeping and not simply deduction of when a product was "likely" in inventory.

IFT recommended to the FDA that product be distinguished at the level of the lot and be traced at the case level. Recognizing that the rate product moves throughout the supply chain–particularly in and out of distribution centers and warehouses–is incredibly high, we hope that technological innovations will enable foods to be traced at the case level in an economical and efficient way.

However, industry will not be alone in needing to make a change. While most recognize that providing records in an electronic format will increase the ability of regulatory agencies to analyze data orders of magnitude faster than today, IFT was surprised to learn that during the course of our study, the FDA's Center for Food Safety and Applied Nutrition was resistant to collecting these types of records. It is discouraging to hear FDA representatives complain about receiving information on paper, when IFT also heard industry report that they hit the "print" button when federal or state authorities asked for information, because hard copies were desired. Clearly, some segments of the food industry have information in an electronic format, and mechanisms for industry to share and government to receive this information must be developed. The FDA has taken positive steps with the Reportable Food Registry and PREDICT tool for import screening, which are both electronic systems.

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Technology Capabilities

Some argue that the technology to manage food system data for the purposes of tracking products is not available. The technologies commercially available may not easily integrate into an existing system and may not readily accommodate paper batch logs, but the third-party systems explored by IFT have phenomenal capabilities. Additionally, many companies already use electronic systems that can be tweaked to enable the capture of data needed to trace products (such as Enterprise Resource Planning, Warehouse Management and accounting systems).

A main reason cited for the lack of implementation of third-party product tracing systems is that individual firms believe they are already in compliance with the Bioterrorism Act and do not view these systems as providing anything the company cannot already do. However, they understandably fail to see the "bigger picture" of product tracing as a system-wide issue that transcends any single firm. With the exception perhaps of vertically integrated supply chains, it is rare to find a company that can truthfully say they are able to trace their product forward and backward. Some systems that "connect the dots" will surely be superior to the pen-and-paper system used today.

Industry Implications: Cost

It is impossible to predict the cost to improve product tracing when the current practices are so incredibly varied and when the "standard" has not been set. Needless to say, most firms will likely need to make some change to their operations, and with change usually comes cost. It is important to note that more rapid and accurate product tracing can save both lives and industries. Saving lives is clearly a primary concern. Being able to identify the cause of illness and remove that suspect product from the marketplace has a public health impact that can be quantified. Some preliminary attempts at assessing how a change in the timing of a traceback could have mitigated the public health burden have been made, but more work should be done in this area.

Although societal benefits can be shown, from the perspective of an individual firm, the impact on the bottom line needs to be quantified. Perhaps one day product tracing will be so accurate that the tomato industry would have been readily exonerated in the 2008 *Salmonella* outbreak. The financial loss to

Sector	Sector Vision	Current ID	Association	Proposed Future			
				Case ID	Data Carrier	Item ID	Data Carrier
Produce	Electronic traceability at case level	Price Look-up	PMA, UFPA	GTIN + lot number	GS1-128	GTIN	GS1 DataBar
Meat & Poultry	Guide consistent application of key traceability principles and processes across the U.S. meat and supply chain	URMIS	mpXML, AMI, NCBA, FMI, NGA/NCC, NTF, NPB, IFDA, NRA	GTIN + lot number	GS1-128 ITF-14	GTIN	GS1 DataBar UPC – A UPC –Type 2
Seafood	Provide guidance to seafood industry on information and processes to support traceability, based upon industry-identified best practices	Defined Numerical Identification	NFI, FMI, NGA, IFDA NRA	GTIN + lot number	GS1-128 ITF-14	GTIN	GS1 DataBar UPC – A UPC – Type 2
Deli, Bakery, Dairy		Defined Numerical Identification	IDDBA, IDFA				
Prepared Foods		Defined Numerical Identification	IDDBA				
Floral	Bring efficiencies to floral industry		PMA, FMI, NGA	GTIN	ITF-14	GTIN	UPC – A
Shelf-stable		GTINs	GMA	Not applicable – already implemented GTIN, U.P.C., ITF			
Foodservice	Drive waste out of the foodservice supply chain; improve product information for customers; establish a foundation for improving food safety and traceability that companies can choose to adopt	GTIN	IFDA, IFMA, NRA	GTIN + additional data TBD	GS1-128 ITF-14	GTIN	UPC ITF-14 GS1-128
Retailers		GTINs	FMI, NGA	Not applicable – already implemented GTIN, U.P.C., ITF			

Table 2: Summary of Product Tracing Initiatives and Practices. Provided courtesy of GS1 US.

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the affected firms could have been mitigated. Another oft-reported tangible benefit from improvements in tracing comes from tighter controls on inventory and being able to link product quality with supplier information. Again, the extent of these benefits is firm-specific and depends on the difference between what is occurring today and what the firm might do in the future.

Product Tracing Challenges

Cost aside, there are other challenges that various members of the food supply chain will face and need to overcome to improve product tracing. Some are firm-specific and relate to changes in the flow of product that may result from the need to add identifiers to products. Many food processing environments are not amenable to things like labels: dust and water are two commonly encountered obstacles that complicate the ability to attach a label to a box. Within the food manufacturing environment, processes have been developed to be highly efficient, and the addition of "another step" specifically for traceability may be a challenge in some operations. Warehouse and distribution operations also deal with high throughput, and the procedures for "picking" products may require some adjustment in order to capture the information needed for product tracing.

Even if the recommendations made by IFT are fully implemented, there will still be some products that are more difficult to trace than others because of their production processes. It is impractical to expect a wheat farmer to mill his own flour or for tomatoes to ripen at exactly the same time. The extent to which facilitating product tracing may compromise efficiency needs to be discussed.

Bulk Product Tracing

The difficulties associated with tracing bulk product have been voiced in many forums. Tracing bulk ingredients such as wheat, sugar, oil, etc. is not impossible, but it's certainly complicated. Some product-storage silos need to be emptied and cleaned regularly. These "break points" enable one to determine the finite (even if high) number of contributors to a given silo. For other products, complete emptying is done rarely, if ever. However, this does not excuse the firm handling the product from keeping appropriate records. In this instance, although the records may show that the pool of constituents is in the hundreds, thousands or more, engineers who understand the way the specific product flows through the silo can provide estimates of the amount of constituent that might reasonably be expected to remain in the system. Obviously, the more time has elapsed since the addition of a specific input, the less of that input would be expected to be in the silo. Dilution is not always a good solution, but having a sense of the relative amount of inputs in a silo or other bulk container could prove very useful when tracking products.

> "…many companies already use electronic systems that can be tweaked to enable the capture of data needed to trace products…"

Commingled/Repacked Products

Tomatoes have served as the poster child for complex product tracing, somewhat unfairly. Conceptually, commingling and repacking are no different than producing multi-ingredient food products. It's just that in the case of commingling, the ingredients happen to be the same. Therefore, tracking commingled product should not be viewed as an exceptional circumstance. Like other multi-ingredient products, the information needed to track incoming ingredients (e.g., multiple lots of tomatoes), such as lot numbers or other identifiers, needs to be recorded and linked to the outgoing product (e.g., a box of tomatoes consisting of multiple sources). The same can be said for rework, which, according to many firms IFT spoke to, is already tracked as an ingredient. Clearly, possible sources and routes of a problem increase in the case of rework, but this is not an excuse to not maintain adequate records.

Recommended Next Steps

Whether or not the House or Senate versions of a food safety bill pass, change is coming. For some, the change could be small. For others, the changes might put them out of business.

For now, IFT hopes firms will consider the recommendations it made to the FDA with respect to the concepts of Critical Tracking Events and Key Data Elements. We believe that identifying the right points at which to capture information (the Critical Tracking Events) and generating or capturing the data needed to trace products (the Key Data Elements–such as lot number, production date, shipper, etc.) will provide a solid foundation for whatever Congress may mandate and the FDA (or the Food Safety and Inspection Service) might implement. ■

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Resources

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Read more about traceability solutions and food safety trends in our Signature Series articles on our Web site at ***www.foodsafetymagazine.com/signature.asp***

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By Robin M. Kalinowski, M.S.

LISTERIA MONOCYTOGENES: Controlling the Hazard in RTE Meat and Poultry Processing Environments

The public health significance of *Listeria monocytogenes* is well known. Listeriosis, the illness caused by *L. monocytogenes*, has a high fatality rate, ranging from 20-30%.[1] High-risk populations include pregnant women and their unborn fetuses, immuno-compromised individuals, cancer patients and the elderly.[2] The manifestations of listeriosis include septicemia, meningitis, encephalitis and intrauterine or cervical infections in pregnant women, which may result in spontaneous abortions or stillbirths. Gastrointestinal or influenza-like symptoms, such as nausea, vomiting, diarrhea and fever, may precede more serious forms of listeriosis or may be the only expressed symptoms.[2]



L. monocytogenes has been recognized as a hazard reasonably likely to occur in cooked, ready-to-eat (RTE) meat and poultry products. Numerous foodborne outbreaks have been linked to the consumption of RTE meats, including hot dogs and deli meats. These products are considered high risk due to the ability of *L. monocytogenes* to multiply at refrigeration temperatures, coupled with the high fatality rate of listeriosis. The U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS) released an interim final rule in 2003 to address public health concerns with regard to *L. monocytogenes* in these products and in processing environments. FSIS used a science-based approach in developing these regulations to address the most at-risk products and processors. Each processor of RTE meat and poultry products could choose one of three alternative programs for the control of *L. monocytogenes* in their products:[3]

Alternative 1: A post-lethality treatment that reduces or eliminates *L. monocytogenes* AND an antimicrobial agent or process that suppresses or limits its growth throughout its shelf-life

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Alternative 2: A post-lethality treatment that reduces or eliminates *L. monocytogenes* OR an antimicrobial agent or process that suppresses or limits its growth throughout its shelf-life

Alternative 3: Sanitation control measures, which may be incorporated in the establishment's Hazard Analysis and Critical Control Points plan, Sanitation Standard Operating Procedures (SSOPs) or prerequisite programs are the only controls to prevent *L. monocytogenes* contamination

For establishments choosing to operate using Alternative 3, consumer protection depends on preventing contamination in those foods in which growth can occur. Intervention strategies and control measures used in these RTE processing environments will be discussed.

Control in the Processing Environment

Processors that rely solely on SSOPs and Good Manufacturing Practices to provide safe, *Listeria*-free products would be considered Alternative 3 facilities. Manufacturing under Alternative 3 is higher risk and will enable more scrutiny from FSIS inspectors; however, if managed properly, these facilities can provide safe products with an extended shelf-life.

Growth of *L. monocytogenes* within a niche or harborage site in the post-processing environment is the major concern with regard to *Listeria* control. Thus, aggressive sanitation and sanitary design of both equipment and facilities are critical to identifying and eliminating niche sites and preventing subsequent product contamination. Cleaning for *Listeria* control includes breakdown of equipment to cleanable levels so that niche sites can be reached. If the equipment is not easily taken apart, niche sites will not be reached, and product and moisture build-up will occur in these uncleanable harborage sites, leading to microbial growth. The American Meat Institute has developed principles for the sanitary design of facilities and equipment.[4] The principles for sanitary design of facilities focus on three broad themes: provide zones of control, keep it cold and control moisture and design to facilitate sanitation. The 10 principles of sanitary design of equipment include the following:[4]

- Cleanable to a microbiological level
- Made of compatible materials
- Accessible for inspection, maintenance, cleaning and sanitation
- No product or liquid collection
- Hollow areas hermetically sealed
- No niches
- Sanitary operational performance
- Hygienic design of maintenance enclosures
- Hygienic compatibility with other plant systems
- Validated cleaning and sanitizing protocols

Once the sanitation and prerequisite programs have been put into place and all personnel are trained, the processing



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environment must be monitored to verify that the programs are working and that harborage sites have not developed. Alternative 3 facilities are required to have an environmental monitoring program in place that includes product contact testing in the post-lethality processing areas to ensure that surfaces are sanitary and free of *L. monocytogenes* or its indicator organisms.[3] The monitoring program must include details on the frequency of testing, size and location of sample sites and should include an explanation of why the testing frequency is adequate to ensure that effective control is maintained.

The establishment should also identify the hold-and-test procedures following a positive result on a product contact surface.[3] An effective monitoring program will identify the source of contamination, eliminate the microorganism from the environment and prevent future contamination by ongoing testing of indicator sites. These indicator sites are non-product contact sites that "indicate" the presence of the microorganism in the processing environment or ancillary areas.

The "zone" concept is widely used in RTE meat and poultry plants for environmental monitoring programs; plant operations are divided into zones based on level of risk. Zone 1 represents product contact surfaces, the highest level of risk. Zone 2 sites are non-product contact sites that are directly adjacent to product contact surfaces and can include control buttons, equipment framework and mechanics' tools. Zone 3 sites are within the post-processing areas and include floors, walls, drains, floor mats, forklifts, pallets and air handling units. Zone 4 sites are not in the post-processing areas, but if unchecked, can lead to cross-contamination of Zones 1, 2 and 3. Zone 4 areas include hallways, loading docks, warehouses, coolers, bathrooms, locker rooms and break rooms.

For a processing facility that is not in control, sampling and testing efforts should be focused on Zone 1 sites to understand the prevalence and to identify and eliminate growth niches. For a processing facility that is in control, sampling and testing focus can move into Zones 2, 3 and 4. Successful processors focus on prevention of contamination by focusing their sampling efforts on indicator sites and then reacting to all positive results, at both product contact and indicator sites, quickly and effectively. Note that Zone 1, or product contact testing, is a requirement for Alternative 3 processors and must be included in the sampling program.

"The environmental sampling program is critical to preventing and controlling *Listeria* in RTE meat and poultry environments."

The environmental sampling program is critical to preventing and controlling *Listeria* in RTE meat and poultry environments. The goal of this program is to find the microorganism. However, ongoing monitoring of the environment would be useless if no efforts were in place to fix the problem once identified. Every successful sampling program must include a corrective action plan to define how the processor will respond to a positive finding. These corrective actions should identify and control the source of the contamination, thereby preventing future contamination.

Intervention Strategies

RTE meat and poultry processors rely on numerous interventions for controlling the transfer, development of niches, and growth of *Listeria* in the manufacturing environment. Industry sharing of best practices and lessons learned has been a key component of the success of this food industry segment. Meat processors have agreed that food safety information should be shared on a non-competitive basis and are willing to share best practices for strategies that work in their facilities through *Listeria* workshops. Although many of these strategies have not been validated in a laboratory setting, processors routinely utilize them and have demonstrated success with regard to *Listeria* control.

Successful processors have learned that controlling *Listeria* on floors will reduce the incidence of contamination of product contact surfaces and that this can be accomplished with adequate cleaning and sanitation. Scrubbing floors with caustic, rinsing and then sanitizing with a high concentration of sanitizer (800–1,000 ppm quaternary ammonium compound as described by Tompkin), is an effective way to do so.[5] Drying floors completely before start up and keeping them dry throughout production is essential. Additionally, the use of various sanitizers in high traffic areas, or areas with a high level of moisture, can improve control. The use of powdered quaternary ammonium compounds has been shared as a best practice that RTE meat processors have implemented and demonstrated successfully in control of *Listeria*.

Other strategies for control of *Listeria* on floors include the use of door foamers, which spray a foam-based sanitizer upon entrance into an RTE area, and sole scrubbers, which combine mechanical action to remove debris from footwear as well as a sanitizer to inactivate microorganisms. These interventions provide control, as demonstrated by plant environmental data. Further research to validate the effectiveness of these systems will aid the industry in defining the optimum usage levels and conditions for use.

Another strategy used by successful processors is the scheduled cleaning of equipment, thus preventing niche development. This can include cooking or steaming equipment that is difficult to clean or is not hygienically designed. Equipment that is small enough can be placed directly in the smokehouse or oven. Some equipment, such as packaging machines, may be too large to move into the smokehouse. A best practice

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that has a demonstrated record of success is steaming the entire packaging line. This technique has proven effective for a packaging line that had an ongoing problem with *Listeria* contamination, but a niche could not be identified. Scheduling this equipment cooking process into the preventative maintenance schedule of the processing facility can prevent the development of a harborage site.

Maintenance tools, if not controlled, can be problematic with regard to contamination and transfer of microorganisms of concern. Maintenance personnel and tools should be dedicated to raw or cooked areas within the processing facility. Hand-held tools should be cleaned and sanitized daily and stored in a sanitary manner. Some processors have reported success with scheduled "cooking" of maintenance tools, which is built into the preventative maintenance schedule.

Brine chill systems are used for chilling certain deli meats and link products. These systems, although high in salt concentration, can easily become contaminated with *Listeria* and can serve as potential harborage sources that can affect multiple lines of packaged product. Brine chill systems pose a significant risk as a source of bacterial contamination, and all products produced with these systems are vulnerable to cross-contamination. The use of citric acid to lower the pH of these brines has proven successful at inactivating *L. monocytogenes* and preventing cross-contamination. Acidifying brine chill systems with citric acid is an effective treatment in controlling *Listeria* in these systems, as long as the pH remains in the 3.0–3.5 range (unpublished data). The pH should be monitored throughout the production day to verify the pH is in the appropriate range.

The RTE meat and poultry industry has come a long way since *L. monocytogenes* was first recognized as a foodborne pathogen. Many of the lessons learned by processors have come the hard way, and they have the scars to prove it. The willingness within this industry segment to share their stories and case studies, lessons learned and best practices developed is a true example of collaboration. ■

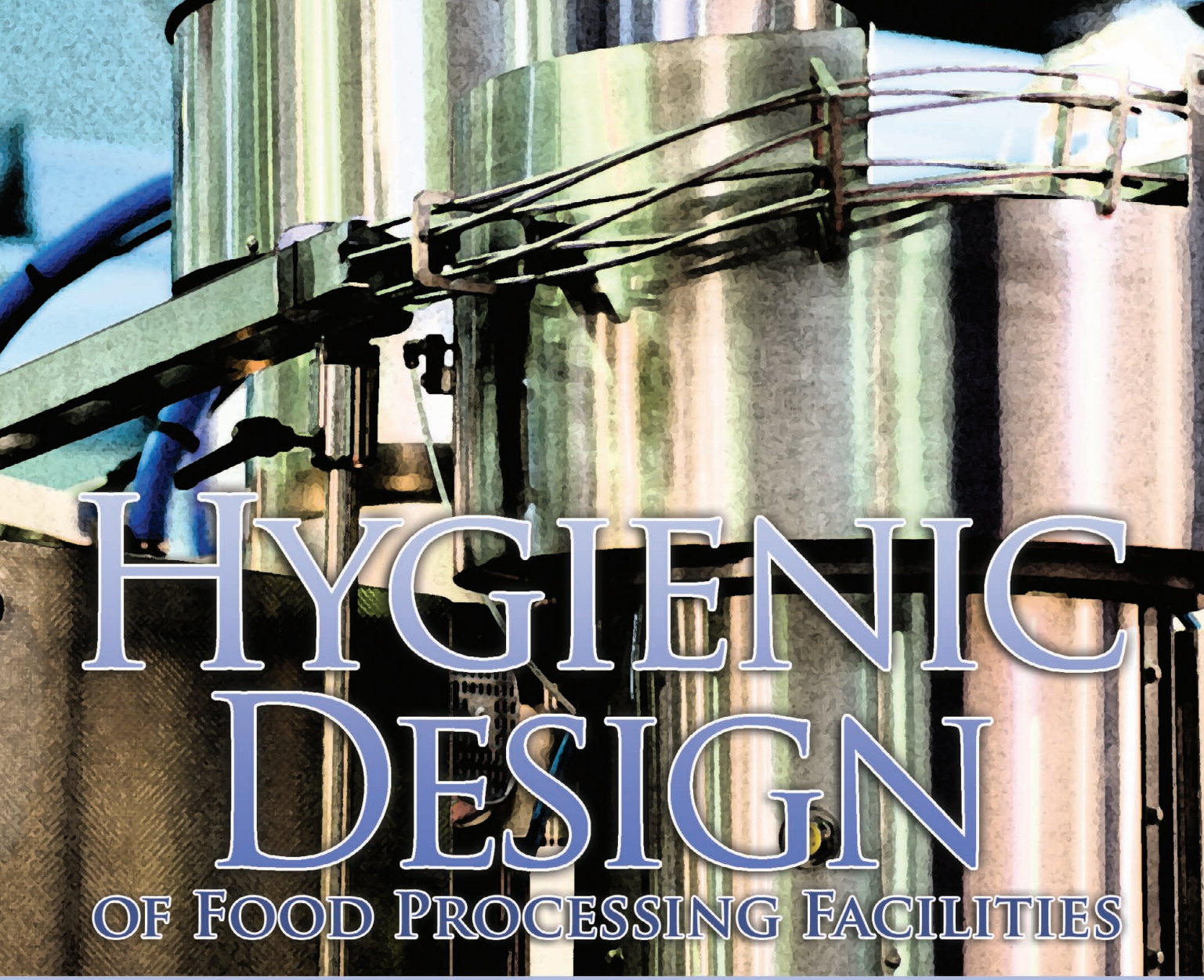
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Hygienic Design

of Food Processing Facilities

By Frank Moerman, M.Sc.

Increasing consumer demand for fresh foods has led to the development of processing and preservation methods that have minimal impact on either the nutritional or sensory properties of foods. Freshly prepared foods often contain less salt, acid, sugar, additives and preservatives. Since the use of mild preservation technologies primarily results in pasteurized products, hygienic processing equipment and a hygienic process environment are needed to prevent microbial, chemical and physical contaminants from affecting these products while preventing product exposure to sources of filth (pests, dust, etc.). Combating product contamination may occur not only at the equipment level but also at the factory level. Incorporation of hygienic design into your food processing facility can prevent development of pests and microbiological niches; avoid product contamination with chemicals (e.g., cleaning agents, lubricants, peeling paint, etc.) and particles (e.g., glass, dust, iron, etc.); facilitate cleaning and sanitation and preserve hygienic conditions both during and after maintenance. The facility infrastructure can be so designed and constructed that it cannot contaminate food products, whether directly or indirectly.

Barrier Technology

To control food safety, providing barriers to food contamination is a generally applied concept. The first barrier refers to outside premises, such as fencing, to prevent unauthorized access to the facility. The access of transport vehicles with raw materials and end-products, personnel, domestic and non-domestic animals should be monitored and controlled. Factory site drainage and storm water collection must be sufficient; areas within a 3-m perimeter of the factory must be kept vegetation free to avoid pest breeding and harborage sites; a 10-cm thick concrete curtain wall around the factory foundation at least 60 cm below ground discourages rodents from entering the building; effluent treatment plants and waste disposal units should be sited such that prevailing winds do not blow microbial and dust aerosols into manufacturing areas.

The second barrier concerns the closing of factory buildings. All entrances/exits (i.e., window and door openings, openings for vents, air circulation lines, floor drains, etc.) must be designed for control over access, flow or exit of personnel, raw and finished food products, air, process aids (process water, process steam, food gases, etc.), waste, utilities (plant cooling and heating water, plant steam, compressed air, electricity, etc.) and pests (insects, birds, rodents, etc.). Floor drains must be screened to avoid rats from entering the food plant via sewers; ventilator openings, including vents in the roof, should be screened to prevent the entry of roof rats, insects and birds; gaps at the entrances of electrical conduits, process and utility piping, which are convenient pathways for roof rats, must be closed.

The third barrier is the segregation of restricted areas (zones) within the plant, each of which have different hygienic requirements and controlled access. The fourth barrier is the processing equipment (including storage and conveying systems), which must have an adequate hygienic design and must be closed to protect the food product from external contamination.

Zoning: A Cornerstone in Prevention of Food Contamination

Zone B is an area in which a basic level of hygienic design requirements suffices. It encompasses areas in which products are produced that are not susceptible to contamination or that are protected in their final packages. A B0 zone is the area outside the buildings within the perimeter of the site where the objective is to control or reduce hazards created by unauthorized personnel entry and hazards created by water, dirt, dust and presence of animals. B1 zones include warehouses that store both raw materials and packed processed products, offices, workshops, power supply areas, canteens and redundant buildings/rooms. The objective for a B1 zone is to control or reduce hazards created by birds and pests.

Zone M is an area in which a medium level of hygiene suffices. It includes process areas where products are produced that are susceptible to contamination, but where the consumer group is not especially sensitive and where no further microbial growth is possible in the product in the supply chain. In this area, product might be exposed to the environment, during sampling and during the opening of equipment to clear blocka-



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ges. The objective for zone M is to control or reduce the creation of hazardous sources that can affect an associated area of higher zone classification. Another objective is the protection of the interior of food processing equipment from contamination when exposed to the atmosphere.

Zone H applies to an area where the highest level of hygiene is required. A "High Hygiene" room, which, in food processing is the equivalent of a cleanroom, must be completely contained. Zone H is typical for open processing, where even short exposure of product to the atmosphere can result in a food safety hazard. Products and ingredients that are processed or stored and are destined for a highly susceptible consumer group (e.g., infant nutrition), are instant in nature or ready for consumption. They must be handled in a refrigerated supply chain, as they are susceptible to growth of pathogenic microorganisms. The objective for H zones is to control all product contamination hazards and to protect the interior of food processing equipment from exposure to atmosphere. Filtered air must be supplied to this area.

> "ZONING AND THE ESTABLISHMENT OF BARRIERS...SHOULD ONLY BE APPLIED WHERE THEIR USE WILL HELP SIGNIFICANTLY TO PROTECT PRODUCTS."

These areas should be limited in size, must have a simple equipment layout to facilitate process, cleaning and maintenance operations and should have utilities located outside. However, investing in an enclosed line that brings barriers very close to the product is more logical than trying to create a complete cleanroom around a partially open line.

Zoning and the establishment of barriers to ensure that product of acceptable hygienic quality is produced should only be applied where their use will help significantly to protect products. Designing the entire factory as a cleanroom is not the purpose of food area segregation to protect both product and consumer. Zoning and barrier technology must be applied in an appropriate and consistent way, thereby avoiding unnecessary investment.

Construction of Facilities: Appropriate Layout

The layout and design of the food factory must be adapted to the hygienic requirements of a given process, packaging or storage area. The interior of the factory must be designed so that the flow of material, personnel, air and waste can proceed in the right direction. As they become incorporated into food products, raw materials and ingredients should move from the 'dirty' to the 'clean' areas. However, the flow of food waste and discarded outer packaging materials should be in the opposite direction. Before building begins, simulation of the flow of people, materials, products and waste can help the designer determine the most appropriate place for installing the process equipment and where the process and utility piping should enter the process area. Even the simulation of maintenance and cleaning operations can be useful to determine the most appropriate factory layout. Graphical computer-aided design and 3D visualization programs can help in the hygienic design, positioning and routing of processes, process supports and utility systems. These programs allow the observer to "walk through" the facility, seeing the inside of the facility from different angles and locations. To save building and renovation costs, potential problems can be solved before the onset of construction. Additionally, in the development of high hygiene areas, computational fluid dynamics can help simulate and visualize expected airflows.

To meet a possible increase of processing activities within the food plant in the future, the building and its food processing support systems should be designed so they can either be expanded, or another building and/or utilities can be added. Oversizing the main utility systems is a common practice. If possible, the factory should also be made adaptable (i.e., the ability to modify the production area for other manufacturing purposes) and versatile (i.e., the ability to do different things within the same room).

Construction of Facilities: Pest Prevention

To exclude flooding and the entry of rodents, factories should be built at a higher level than the ground outside. Exterior doors should not open directly into production areas, and windows should be absent from food processing areas. The number of loading docks should be minimal and be 1–1.2 m above ground level. Preferably, outside docks should have an overhanging lip, with smooth and uncluttered surfaces that are sloped slightly away from the building to encourage water runoff. Areas beneath docks should not provide harborages for pests, should be paved and should drain adequately. To provide protection for products and raw materials, docks can be shielded from the elements by roofs or canopies. However, these structures can become a serious sanitation problem due to roosting or nesting of birds. Bird spikes or nets can solve that problem. To prevent the entry of insects, dock openings should be provided with plastic strips or air curtains, and external lighting to illuminate these factory entrances should be placed in locations away from the factory building. Intruding insects can still be attracted and killed within the food factory by strategically positioned ultraviolet (UV) light electric grids or adhesive glue board traps.

Construction of Facilities: Interior Hygienic Design

Construction Materials

Construction materials for equipment and utility piping should be hygienic (non-absorbent, non-toxic and cleanable), chemical-resistant (to product, process chemicals and sanitizing agents), physically durable (unbreakable, resistant to moisture, cold, abrasion and chipping) and easy to maintain. Materials used to construct process and utility systems located in the non-food contact area may be of a lower grade than those applied in the food contact zone. Surfaces that are frequently wet

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should not be painted as the paint can crack and chip.

Lead, mercury and cadmium should not be used within the factory. However, as part of many electric components, it is very difficult to exclude their presence. In the food contact area, electric components must always be enclosed in junction boxes, casings, closed cable housings, cabinets, etc. or should be installed in non-product contact zones or in technical corridors. Alloys for food contact may only contain aluminium, chromium, copper, gold, iron, molybdenum, nickel, platinum, silver, titanium, zinc, carbon, etc. However, zinc, copper, aluminium, bronze, brass, carbon and galvanized and painted steel have poor resistance to detergents, disinfectants, acidic food and steam and must be avoided in food contact areas.

Polytetrafluoroethylene, polyethersulfone, polyvinylidene fluoride, phenol-formaldehyde, urea-formaldehyde, melamine-formaldehyde, epoxy and unsaturated polyester resins are used in the construction of electric components, while other plastics like polypropylene (PP), low-density polyethylene (PE), polyvinyl chloride (PVC), polyurethane (PU), ethylene propylene diene monomer (EPDM), silicone, etc. are applied as jacket materials for electrical cables or for the construction of pneumatic hoses and compressed air tubing. PP, PE and PVC are also used to construct drain pipes, while shields of polycarbonate can protect the food area below light sources from shattered glass after accidental breakage of lamps. Silicone, nitrile, PU, EPDM and butyl rubber are largely used as materials for gaskets, seals, etc. Epoxy is widely used as floor, wall and ceiling coatings. Remember that many plastics perform differently at -25 °C than they do at 20 °C.

> "THE LAYOUT AND DESIGN OF THE FOOD FACTORY MUST BE ADAPTED TO THE HYGIENIC REQUIREMENTS OF A GIVEN PROCESS, PACKAGING OR STORAGE AREA."

Integration of Piping

Utility piping in technical corridors or zone H areas should be integrated into wall compartments or the ceiling. If this is not possible, it is recommended to use open racks, fixed to the ceiling, or walls and columns close to the ceiling. However, sufficient clearance must be provided between pipe runs and adjacent surfaces so that both are readily accessible for cleaning and maintenance. The pipe racks must be designed hygienically to minimize the presence of horizontal ledges, crevices or gaps where inaccessible dirt can accumulate.

Food processing support piping should be directly routed from service rooms to process areas and should always be logical and simple. The amount of utility piping should be minimized and should have–like process piping–a slope of 1/200 to 1/100. Especially in process, hot water and process steam piping, standing "pools" of liquid that can support the growth of microorganisms must be avoided. To remove condensate, steam traps should be located at all low, convenient points along any extended pipe length. Steam purges for relief of steam condensate in a drain should be closely connected to that drain. In open systems, the steam vapor coming out of a drain can cause humidity and odor problems within the factory. Discharge of condensate from the system should be via an air break to prevent back-siphonage. Neither process nor utility piping should have dead legs.

Like process piping, utility piping should be grouped together in easily accessible pipe trains whenever possible. The points of use should also be grouped, in an attempt to minimize individual ceiling drops. Vertical entrance of piping into the equipment or equipment jacket is more hygienic than horizontal utility piping runs. Running of process and utility piping over open equipment in food preparation areas cannot be accepted, and nesting of ductwork should be avoided. Piping should not clutter the ceiling. When necessary, suspended racks that run over a product zone shall be equipped with a drip pan that protects the product zone below and can be readily removed for cleaning. Bumper guard construction can also be installed in heavy traffic areas to protect piping from external mechanical forces.

Piping should be installed at least 6 cm from walls and floors to encourage thorough cleaning around it. Piping in corners should be avoided, as it hampers thorough cleaning. Process equipment shall be installed such that enough space is provided to facilitate pipe cleaning.

As piping (utility and process) can affect or disrupt the airflow pattern in zone H rooms, a fog test can control airflow patterns. The geometry of the utility piping can destroy the desired air pattern (e.g., piping with a square or rectangular profile is less favorable than circular). Square and rectangular shapes create turbulence and depressions where dust can accumulate, but cylindrical profiles make cleaning easier.

Penetration of Piping through Walls, Ceilings and Floors

Piping that transports dirty fluids should not run in the vicinity of or cross utilities that transport process aids, especially if these process aids are in direct contact with the food to be processed. Like process piping, food processing support piping should run unidirectionally, with the support piping running from the cleanest area toward the least clean areas. Support systems should deliver a certain process aid first in the process area with the highest hygienic risk (zone H) and last in the zone of lowest hygienic risk (zone L).

Pipeline penetration through walls, ceilings and floors should be minimized, as holes in these areas can lead to sanitation problems and can invite the entry of insects and rodents. Openings in floors for pipes should be guarded with a sleeve to avoid spill of cleaning solutions onto a lower floor. When several pipes penetrate the floor, a larger curbed floor can replace several pipe sleeves to improve the cleanability of the surrounding process environment. However, that curbed floor may create a large opening where pests may harbor, and where dirt, water, etc. may accumulate. It must be a completely closed curb with a cover that leaves no gap around the penetrating piping.

Holes in walls for pipe traverse need not to be sealed water-

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with a cover that leaves no gap around the penetrating piping.

Holes in walls for pipe traverse need not to be sealed water- and air-tight when both sides of the wall are in rooms of the same hygienic zoning, but any opening should be large enough for access and cleaning. However, if a wall separates rooms of different hygienic zoning, all holes for pipe traverse must be sealed. The exterior surfaces of the pipes that traverse walls or ceilings should then have water- and air-tight contact with the wall or ceiling. Foaming-in-place is an appropriate method to close the gaps formed between pipe surfaces and walls as are the applications of plastic caps around the piping and flashing flanges. If running of process and utility piping through walls or ceilings in zone H rooms cannot be avoided, the apertures through the walls and ceilings shall be properly closed against air leakage, as they give excessive air volume losses which may affect product.

> "HYGIENIC FOOD FACTORY DESIGN STARTS WITH THE SELECTION OF AN APPROPRIATE LOCATION AND THE APPLICATION OF A HYGIENIC BUILDING CONCEPT THAT PREVENTS THE ENTRY OF PESTS."

Sanitary Insulation of Piping

Hot piping should not run in the neighborhood of piping that transports cold food products, cold process water, etc. The warm-up of these cold liquids can give rise to the growth of food pathogens. Insulation of hot piping is required, not only to economize on energy, but also to prevent excessive heating of the food production environment above acceptable temperatures. Poorly insulated ethylene glycol and cold/chilled water piping can sweat or be covered with ice, resulting in dripping water. To avoid ingress of dust, vermin, etc. into the insulation, it is highly recommended fully welded metal cladding or plastic covering be installed. It should be impossible to walk on the insulation during maintenance. Damage to insulation can be inhibited by covering the pipe insulation with a smooth, hard, non-electrostatic, plastic cover, rather than steel sheet cladding.

Hygienically Designed Transfer Panels

Flexible hoses can be used for performing transfers within a given process area. However, hoses are impractical to perform transfers between rooms, especially if these rooms have a different level of "cleanliness." To make connections between different processing units in adjacent rooms, the use of hygienically designed transfer panels is recommended. Interconnection between the different ports should be made with sanitary U- and J-bends. Piping behind the transfer panel and the panel ports must be sloped to ensure proper drainage of residual liquid toward a drain pan. For the same reason, the whole transfer panel can tip a little bit forward. Ports should be capped when not in use to prevent any potential spill or contamination.

Chemical and Wear-resistant Floors

Floors should be sloped toward drains and provided with curbed wall floor junctions, with the curbs having a 30-degree slope to prevent accumulation of water, dust or soil.

Concrete flooring, including the high-strength granolithic concrete finishes, are especially suitable in warehouses where excellent resistance to heavy traffic is critical. However, untreated concrete can be dusty if dry and highly susceptible to damage from water and acids when wet. Concrete flooring is not recommended for high-care production areas, because it can spall and absorb water and nutrients, allowing microbial growth below the surface.

Epoxy flooring provides a durable, seamless, chemical-resistant and readily cleanable surface. However, over time the coating can crack and buckle due to exposure to cleaning chemicals or wear caused by heavy traffic. Once this happens, moisture pockets under the coating can create a microbiological niche.

Tile flooring is an excellent surface for food plants. However, with heavy wear and in more aggressive cleaning environments, tiles may lose some of their grouting, allowing the penetration of water beneath them. Plastic or asphalt membranes may be laid between the underlying concrete surface and the tiles. Brick floors also may be satisfactory but tend to be somewhat fragile and, unless vitrified, permit water penetration.

Welded PVC sheets have excellent chemical resistance. However, they are not suitable in hot and wet areas, and the welded PVC may be damaged by heavy cart traffic. Steel plates may be used on balconies, for example, and on loading docks and walkways in the vicinity of the process. However, they may corrode and are difficult to bond to concrete. Wood floors are satisfactory in packing and warehouse areas; however, the wood should be impregnated and coated with a durable plastic such as PU. Generally, wood floors may become worn, porous and absorbent, requiring expensive maintenance, and thus are not typically installed in modern food plants.

Pocket-free Drains

Drains should have appropriate capacity to avoid "ponding" of water and hence contamination in the area to be drained. The drain bodies must be free of pockets that can hold food soil; otherwise, they will cause odor problems. Only drains with an internal P-trap and atmospheric break should be used. P-traps create a water-lock that keeps sewer gases out of the plant.

Balanced Air Supply and Exhaust System

Exhaust systems should have sufficient capacity to remove excess heat, dust, vapor, aerosols, odors and bioburden from process rooms. However, a positive overpressure must always be maintained. The supply of filtered air in the room by the heating-ventilation-air conditioning system must thus be large enough, otherwise the exhaust system will attempt to draw the required amount of air from adjacent less clean areas through doorways and windows. Exhaust fans must be located outside the building to maintain a negative pressure in the portion of the duct system located within the building. If they are installed

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in the exhaust hood, the exhaust air is pushed through the duct and not pulled out. By pushing vapors, fumes, etc. through that duct, the system puts the exhaust duct under positive pressure, which can force dirty air back into the room through holes and gaps in the duct work.

Hygienically Designed Lighting

Lighting must illuminate horizontal and vertical working surfaces evenly, without causing glare and at an intensity of about 300–500 lux at normal working height. Walls and ceilings should be light-colored because that permits fast detection of dirt and soil on their surfaces. In contrast, dark-colored walls and floors require additional lighting.

Preference should be given to lighting mounted on ceilings rather than on walls, because process equipment, storage racks, etc. can form shadows that make cleaning and inspection of floor, walls or ceilings difficult. For the same reason, overhead piping may not obstruct lighting.

Selected lighting should produce little heat and UV light to prevent attraction of insects. Because high-intensity discharge lamps (metal halide, and high- and low- pressure sodium lamps) have high penetration depth, they are used as high-bay lighting in warehouses; fluorescent luminaires are preferred as low-bay lighting, giving good illumination with less glare when covered with a prismatic cover or opalescent diffusing panel.

Lighting systems and their supports may not create horizontal ledges, legs or surfaces. To avoid projections that can accumulate dust, they can be built into the ceiling or wall with a hermetically closed seal, a procedure that is typical for cleanroom areas where lamps are changed via the technical area.

Hygienic Supply and Application of Electricity

In zone M areas, installing individual cables or multiple cables of small diameter, sharing the same route, in conduits is recommended. When two or more cables partly share a common route but go to different termination points, the creation of unsealable openings that allow the cable(s) to enter or exit the conduit is possible. However, this practice is only recommended for short distances. For long distances, straight line, non-bundled electric cables should be mounted on wire trays, preferably separated from each other. Vertical cable trays are less prone to dust accumulation, and are more accessible for inspection and cleaning. The use of horizontal racks for electrical cabling should be minimized, or they should be protected by a removable lid or installed vertically (on their side) to minimize horizontal surfaces.

When two or more cables partly share a common route, but go to different termination points, unsealable openings allowing cable(s) to enter or exit the conduit should be avoided. Conduits should be suitably sealed at both ends with a proprietary cable/sealing gland where a cable does pass through. In the food contact and splash areas, cables can also be protected from dirt, penetrating liquid and damage by encapsulating them in hermetically closed cable housings. However, the use of pipe rather than conduit should be discouraged because of the difficulties in maintaining the integrity of the piping system at cable entries and exits. Cable mounting in pipes still creates a hollow body and hence a hygienic risk.

Electric components should be enclosed in dust- and water-tight cabinets or field boxes with all connections made at the bottom. Connections of cables and wires to housings must be sealed. The enclosures should be spaced away from equipment or walls and should be provided with an easily drainable 30° top roof. The heat generated by the electrical installations within these enclosures, and concomitantly the dust that penetrates the electrical installation during its cooling by means of fans, should be ventilated toward a technical area or a central ventilation system.

Control Panels

Control panels with high ingress protection rating should be provided with hygienically designed control and indicator devices. However, the more modern and hygienic membrane panels or touch-screen display panels now often replace these older, non-computer-based control panels.

Conclusions

Many food manufacturers only make use of the classic food preservation approach to control food safety. In the past two decades, however, the European Hygienic Engineering & Design Group has demonstrated that hygienic design of food process equipment and factories can contribute significantly to enhanced food safety. Hygienic food factory design starts with the selection of an appropriate location and the application of a hygienic building concept that prevents the entry of pests. The factory layout must permit the correct flow of materials, waste, air and personnel without compromising food safety as well as the installation of hygienic zones that offer maximal protection to the food produced. Process equipment and process and utility piping must be designed from food-grade materials that are compatible with the food product produced and the cleaning agents and disinfectants applied to sanitize the production environment. To avoid the introduction of new contaminants, equipment and piping must be hygienically integrated within the factory's premises. Walls, ceilings and floors must have an appropriate finish, lighting must provide sufficient illumination and drains should guarantee proper drainage to facilitate cleaning and to maintain hygienic conditions within the factory. The aim of this article is to serve as an introduction to proper hygienic food facility design. ■

Frank Moerman *received his M.Sc. in bioengineering from the University of Ghent in Belgium. In 2002, he became a member of the European Hygienic Engineering and Design Group (EHEDG) responsible for Belgium. More about EHEDG can be found at www.ehedg.org.*

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portance of record review. Management must develop a program to review all calibration records deemed critical to quality and safety by the risk assessment. Procedures on how to review the records should be developed and implemented. In addition, employees who conduct the reviews must be trained on said procedures. For CCPs, review of the records for calibrating the instruments would be incorporated into the HACCP plan.

Processors should also establish programs to verify that the calibration program is being properly followed. Persons doing these internal audits should be independent of this area. For example, if calibration is managed by the production group, the auditor could be drawn from quality, warehouse operations or elsewhere. The verification activities should include the following elements:

- *Procedures* – The auditors should make sure that the persons responsible for doing work are following established procedures. Auditors should use procedures and work instructions as a guide when doing this phase of the audit. Auditors should also look to see that calibrations were carried out according to schedule.
- *Competencies/Training* – This starts with the auditor reviewing the training records. However, training should lead to competencies. To verify the latter, the auditor needs to observe the individual doing the calibration to determine if the person is actually following the procedure. When work is done by an outside agency, confirm that the group doing the work is competent and that there is some protocol for selecting and evaluating potential contractors.
- *Records* – The auditors should also review records, which would include looking for deviations and corrective actions. The review should also look for evidence of management review.

The individuals conducting these audits must be trained on audit procedures. In addition, records of training must be maintained. This is something that may be done internally or through an outside agency. Many processors send their people to programs that certify them as ISO auditors. Again, this is a choice that each company should make.

Evaluating the Program

Calibration and, in fact, all programs should be evaluated on a regular basis. The program should be reviewed by the plant manager and the management team at least once a year. The review should draw heavily on the verification activities and on the company's performance related to quality and safety goals. The objective of this exercise is to look at the program as it exists and look for ways to enhance it. One of the results of the management review should be an improvement plan that includes programs, assigned responsibilities, timelines to complete the project and the resources needed to complete the work. If such a program has been operating, the review should also address past improvement plans, their status and success or failure. This is an essential element for continuous improvement and an integral element of ISO 22000.

Making the Calibration Program "Audit Friendly"

As mentioned, calibration is an integral part of a processor's quality and safety program. Getting the program organized, particularly ensuring that it is managed by one person rather than many, will help make the program "audit friendly." The master calibration schedule provides users and auditors with an organized summary of the program. In fact, to make it even easier to manage, processors should add one more field: the location of the records for that instrument. Of course, the best means for getting everything in one place is an electronic system. As noted, maintenance management software programs are a tool that can capture the whole program; so rather than looking at piles of records, one can audit the complete program by sitting in one place in front of a computer. If electronic systems are used, the computer should have security systems that meet 21 CRF 11, the electronic recordkeeping requirements.

So, take a long look at how calibration programs are being managed and ask yourself, "Is this the best we can do?" My guess is that you can do better. ■

Richard F. Stier *is a consulting food scientist with international experience in food safety (HACCP), plant sanitation, quality systems, process optimization, GMP compliance and microbiology. Among his many affiliations, he is a member of the Institute of Food Technologists and an editorial advisor to* Food Safety Magazine*. He can be reached at rickstier4@aol.com.*

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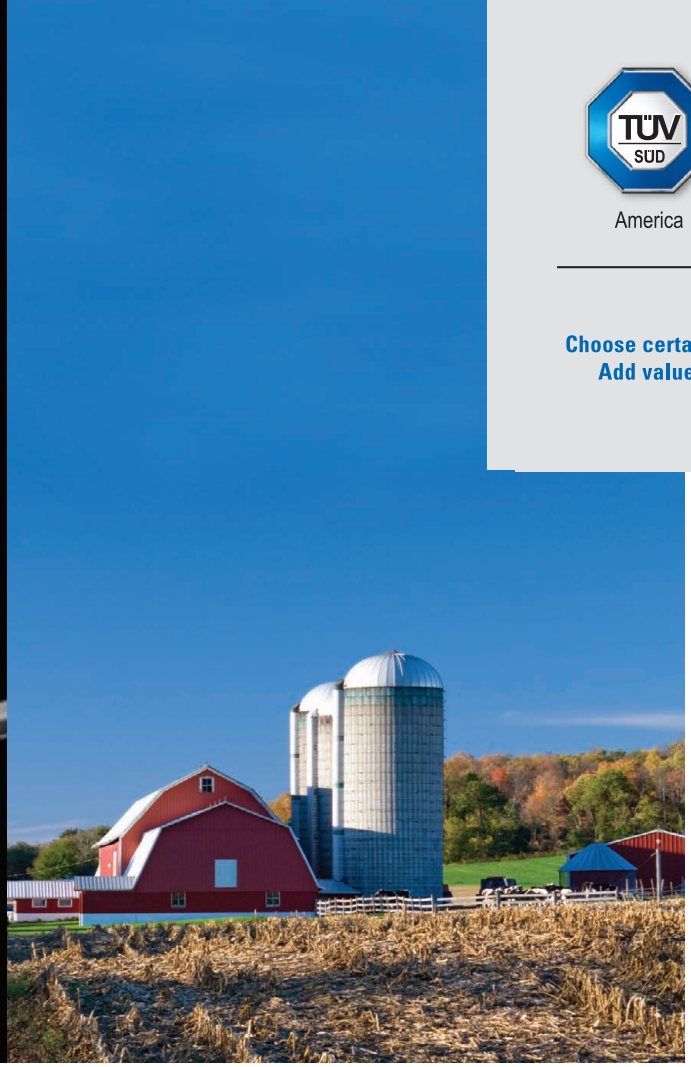
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